PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Brian J. Brown, Michael Davis, David Friesen, Timothy J. Ley and Sean Skubitz**
Application No.:	**10/705273**
Filed:	**November 10, 2003**
For:	**Improved Longitudinally Flexible Expandable Stent**
Examiner:	**Vy Q. Bui**
Group Art Unit:	**3773**

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Alexandria, VA 22313-1450

Docket No.: S63.2N-6769-US03

APPEAL BRIEF

This is an Appeal Brief for the above-identified application. A Notice of Appeal was filed in this case on March 3, 2010.

The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

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(i) Real Party in Interest

This Application is owned by Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

For the purpose of complying with the requirements of 37 C.F.R. § 41.37(c)(1)(ii), the following chain of priority is set forth below, followed by a listing and explanation of related Appeals and/or Interferences.

The Immediate Application is a continuation of Application No. 09/197,278. Application No. 09/197,278 is a continuation-in-part of Application No. 08/511,076. In turn, Application No. 08/511,076 is a continuation-in-part of Application No. 08/396,569.

Application No. 08/396,569 has the following descendants (in no particular order):

09/878,596; 10/705,273; 10/817,508; 10/918,971; 11/519,552; 09/599,674; 08/511,076; 09/122,431; 09/666,866; 09/934,178; 10/194,854; 10/728,513; 10/800,572; 09/197,278; 09/957,983; 10/063,179; 10/996,088; 11/781,031; and 12/205,394.

The Immediate Application was amended pursuant to a Preliminary Amendment filed concurrently with the Application on November 10, 2003 in an effort to interfere with US 6,540,775 to Fischell et al. The Preliminary Amendment of November 10, 2003 is herein attached as Appendix B. The claims of the Preliminary Amendment have subsequently been amended and an interference has **not** been declared.

An Appeal to the BPAI was taken in Application No. 10/800,572 with the filing of a Notice of Appeal on July 28, 2008, and an Appeal Brief on August 29, 2008. No decision was rendered by the Board as prosecution was re-opened on November 28, 2008. Then, on October 16, 2009, a Notice of Appeal was filed and an Appeal Brief submitted on December 16, 2009. As of the time of this writing, no response or other communication has yet been sent by the Office in response to the Appeal Brief.

An Appeal to the BPAI was taken in Application No. 09/934,178 with the filing of a Notice of Appeal on November 21, 2006. No decision was rendered by the Board as an RCE was subsequently filed on January 19, 2007, thereby disposing of the Appeal. Subsequently, on December 09, 2009 an Appeal to the BPAI was taken with the filing of a Notice of Appeal, a Request for Pre-Appeal Conference, and an accompanying Brief. A Pre-Appeal Conference Decision was mailed on March 01, 2010 upholding the rejections.

Subsequently, on March 31, 2010 an Appeal Brief was submitted. No decision or other communication has yet been sent by the Office in response to the Appeal Brief.

An Appeal to the BPAI was taken in Application No. 09/666,866 with the filing of a Notice of Appeal on August 23, 2004, and an Appeal Brief on November 23, 2004. No decision was rendered by the Board as prosecution was re-opened on February 4, 2005.

An Appeal to the BPAI was taken in Application No. 10/063,179 with the filing of a Notice of Appeal on June 25, 2008, and an Appeal Brief on July 10, 2008. The Examiner's Answer was mailed on March 03, 2009 and a Reply Brief was filed on May 04, 2009. As of the time of this writing, no Decision has yet been rendered by the BPAI.

In addition, with respect to Application No. 10/063,179, OrbusNeich Medical Inc. commenced litigation in the eastern District of Virginia (Docket number 2:09CV115-HCM/JEB) on March 16, 2009 against Boston Scientific Corporation. Neither the instant application, nor Application No. 10/063,179, was mentioned in the complaint. The litigation pertains, *inter alia*, to Boston Scientific's Literté™ stent. The case was transferred to the District of Massachusetts on June 08, 2009 and given a Docket number of 1:09cv10962.

An Appeal to the BPAI was taken in Application No. 08/511,076 with the filing of a Notice of Appeal on April 07, 1997, and an Appeal Brief on May 29, 1997. The Board issued a decision on September 25, 2001, a copy of which is included herewith in the Related Proceedings Appendix.

(iii) Status of Claims

Claims 38, 39, 42, 43, 45, 46, and 57-70 are pending in this application, stand finally rejected, and are the subject of this appeal. Claims 40, 41, and 44 have been withdrawn. Claims 1-37 and 47-56 have been canceled.

(iv) Status of Amendments

No amendments have been filed subsequent to the final rejection of November 11, 2009.

(v) Summary of Claimed Subject Matter

Independent claim 38 recites a stent in the form of a thin-walled, cylindrical tube with a longitudinal axis 895. *E.g.*, figs. 3, 10 below. The stent comprises a multiplicity of interior circumferential sets of strut members, *e.g.*, 820, and one end circumferential set of strut members, *e.g.*, 820, at each end of the two longitudinal ends of the stent. *E.g.,* figs. 3, 10. Each interior circumferential set of strut members and each end circumferential set of strut members have a first end, *e.g.*, 836, and a second end, *e.g.*, 840. Each interior circumferential set of strut members includes a plurality of strut members, *e.g.*, 123, 135, connected by curved sections 836, 840. The curved sections 836, 840 are located at the first and second ends and the curved sections 836, 840 include connected curved sections and unconnected curved sections. *E.g.*, figs. 3, 10 and page 8, lines 19-22 of the Application as-filed (included as Appendix A[1], hereinafter "app. A"). Each two adjacent strut members, *e.g.*, 137, are connected by a single curved section. *E.g.*, figs. 3, 10. The strut members 123, 135 include at least one connected strut member consisting of a long diagonal section 135 having a longitudinal length fixedly attached to a connected curved section. *E.g.*, figs. 3, 10. Each connected curved section is joined by means of a longitudinal connecting link, *e.g.*, 144, 844, to one connected curved section of an adjacent circumferential set of strut members 820. All connecting links 144, 844 that connected adjacent circumferential sets of strut members are connected at a connected curved section 836, 840. *E.g.*, figs. 3, 10. The strut members 123, 135, also include at least one unconnected strut member consisting of a short diagonal section 123 having a longitudinal length fixedly joined to an unconnected curved section.

Dependent claim 39 recites the stent of claim 38 wherein the longitudinal connecting link 844 is straight. *E.g.*, fig. 10.

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[1] The page numbering of the Application as-filed has been retained and does not correspond to the page numbering of this Brief.

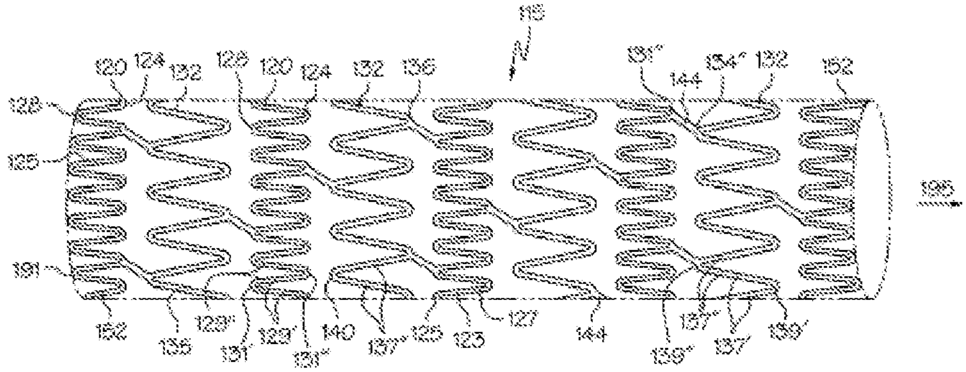


FIG. 3

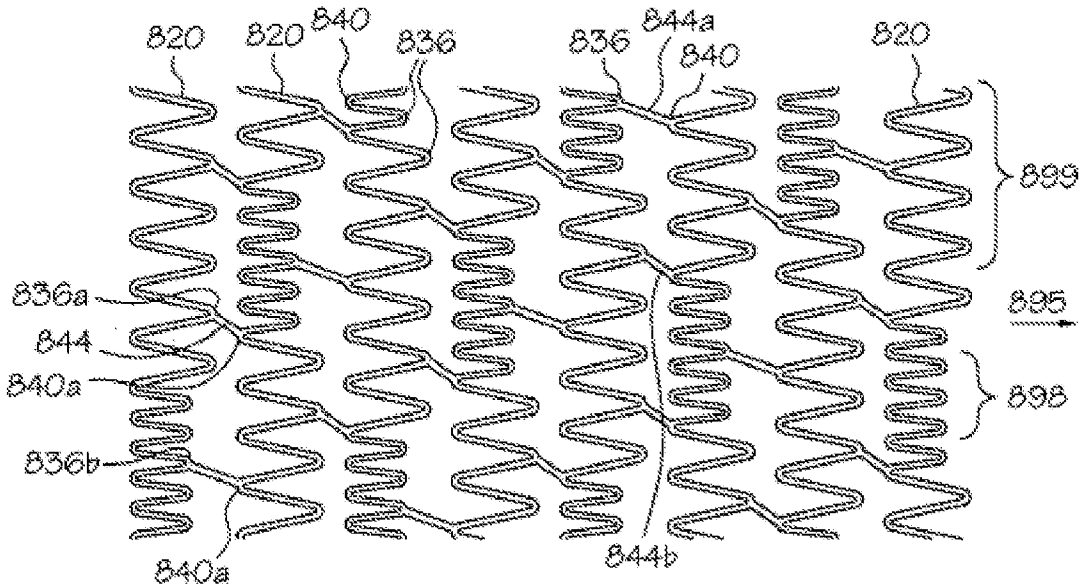


FIG. 10

<u>Dependent claim 42</u> recites the stent of claim 38 wherein there are three longitudinal connecting links 844 that join each adjacent pair of circumferential sets of strut members 820. *E.g.*, fig. 10 and app. A, page 8, line 22.

<u>Dependent claim 43</u> recites the stent of claim 38 wherein there are five longitudinal connecting links 844 that join each adjacent pair of circumferential sets of strut members 820. App. A, claim 17 as-filed.

Independent claim 58 recites a cylindrical expandable stent. The stent comprises a plurality of undulating band-like elements 820 aligned on a common longitudinal axis 895 to define a generally tubular stent body having a first end and a second end. *E.g.*, figs. 3, 10. Each band-like element 820 has alternating peaks 836 and troughs 840. *E.g.*, fig. 10. The peaks 836 and troughs 840 take a generally longitudinal direction along the cylinder. *E.g.*, fig. 10 and app. A, page 7, lines 30-31. The peaks 836 of each band-like element 820 comprise peaks of a first amplitude 836b and peaks of a second amplitude 836a, the first amplitude 836b being less than the second amplitude 836a. *E.g.*, fig. 10 and app. A, page 12, lines 10-14. The expandable stent further comprises a plurality of interconnecting elements 844. *E.g.*, fig. 10 and app. A, page 12, lines 9-10. Each interconnecting element 844 has a first end and a second end, the first and second ends extend from adjacent band-like elements 820. *Id.* The first and second ends are displaced circumferentially along the stent. *E.g.*, fig. 10; *see also* app. A, page 12, lines 19-23.

Dependent claim 59 recites the stent of claim 58, wherein peaks 836 of the same amplitude are grouped together within a band-like element 820. *E.g.*, fig. 10 and app. A, page 12, lines 4-6.

Dependent claim 60 recites the stent of claim 59, wherein peaks 836 having the first amplitude on a first band-like element are circumferentially offset from peaks having the first amplitude on a second band-like element. *E.g.*, fig. 10.

Dependent claim 61 recites the stent of claim 58, wherein each of the plurality of band-like elements 820 has a first region 898 having a first wavelength and a second region 899 having a second wavelength, wherein the first wavelength is less than the second wavelength. *E.g.*, fig. 10 and app. A, page 12, lines 23-25.

Dependent claim 63 recites the stent of claim 58 wherein each of the plurality of interconnecting elements 844 is substantially straight. *E.g.*, fig. 10.

Dependent claim 64 recites the stent of claim 58, wherein the plurality of interconnecting elements 844 is comprised of first interconnecting elements having a first length 844a and second interconnecting elements having a second length 844b, wherein the first length is longer than the second length. *E.g.*, fig. 10 and app. A, page 12, lines 14-19.

Dependent claim 65 recites the stent of claim 64, wherein interconnecting elements having a first length 844a extend from the peaks having the first amplitude 836b on a band-like element to a trough 840a on an adjacent band-like element. *E.g.*, fig. 10 and app. A, page 12, lines 10-19.

Dependent claim 66 recites the stent of claim 58 wherein the peaks of the second amplitude 836a extend further toward the first end of the stent than the peaks of the first amplitude 836b. *E.g.*, fig. 10.

Independent claim 67 recites a stent comprising a multiplicity of interior sets of strut members, *e.g.*, 820. Each interior set, *e.g.*, 820, having a first end and a second end and a plurality of strut members, *e.g.*, 123, 135, which are connected one to the other. *E.g.*, figs. 3, 10. Adjacent strut members 123, 135 within an interior set 820 are arranged in pairs of strut members, *e.g.*, 137 wherein some of the strut pairs include a longer strut member 135 and a shorter strut member 123. *E.g.*, figs. 3, 10. Adjacent interior sets, *e.g.*, 820, are connected to one another via interconnecting elements 844. *Id.* The interconnecting elements 844 are arranged such that each interconnecting element 844 which connects to an interior set, *e.g.*, 820, adjacent its first end is connected to an interconnecting element 844 which connects to an interior set, *e.g.*, 820, adjacent its second end via a pathway of only three connected strut members, *e.g.*, 123, 135 of the interior set 820.

Dependent claim 68 recites the stent of claim 67 wherein some of the interconnecting members 844 extend from strut pairs having a longer strut member and a shorter strut member. *E.g.*, fig. 10.

Dependent claim 69 recites the stent of claim 68 wherein the first and second ends of each interconnecting member 844 are circumferentially and longitudinally offset from one another. *Id.*

Dependent claim 70 recites the stent of claim 67 wherein said pathway includes two strut members of one length and one strut member of a different length. *Id.*

(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Did the Examiner err in rejecting claims 38, 42, 43, 45, 58-60, and 65 under 35 USC § 102(e) over Fischell (US 6,190,403)?

Issue 2: Did the Examiner err in rejecting claims 39 and 63 under 35 USC § 103(a) over Fischell (US 6,190,403) in view of Kanesaka (US 5,810,872)?

Issue 3: Did the Examiner err in rejecting claim 46 under 35 USC § 103(a) over Fischell (US 6,190,403) in view of Anderson (US 5,800,526)?

Issue 4: Did the Examiner err in rejecting claims 57, 61, 62, 64, and 66 under 35 USC § 103(a) over Fischell (US 6,190,403)?

Issue 5: Did the Examiner err in rejecting claims 67-70 under 35 USC § 102(e) over Al-Saadon (US 5,755,776)?

(vii) Argument

<u>Issue 1: The Examiner erred in rejecting claims 38, 42, 43, 45, 58-60, and 65 under 35 USC § 102(e) over Fischell (US 6,190,403).</u>

The rejections asserted by the Examiner under 35 USC § 102(e) are *traversed* because the applied reference does not disclose a stent as recited in rejected claims 38, 42, 43, 45, 58-60, and 65.

<u>Independent Claim 38 and Dependent Claims 42, 43, and 45</u>

Independent claim 38 recites, in-part:

> each interior circumferential set of strut members including a plurality of strut members connected by curved sections, the curved sections located at the first and second ends, the curved sections including connected curved sections and unconnected curved sections . . . strut members also including at least one unconnected strut member consisting of a short diagonal section having a longitudinal length fixedly joined to an unconnected curved section.

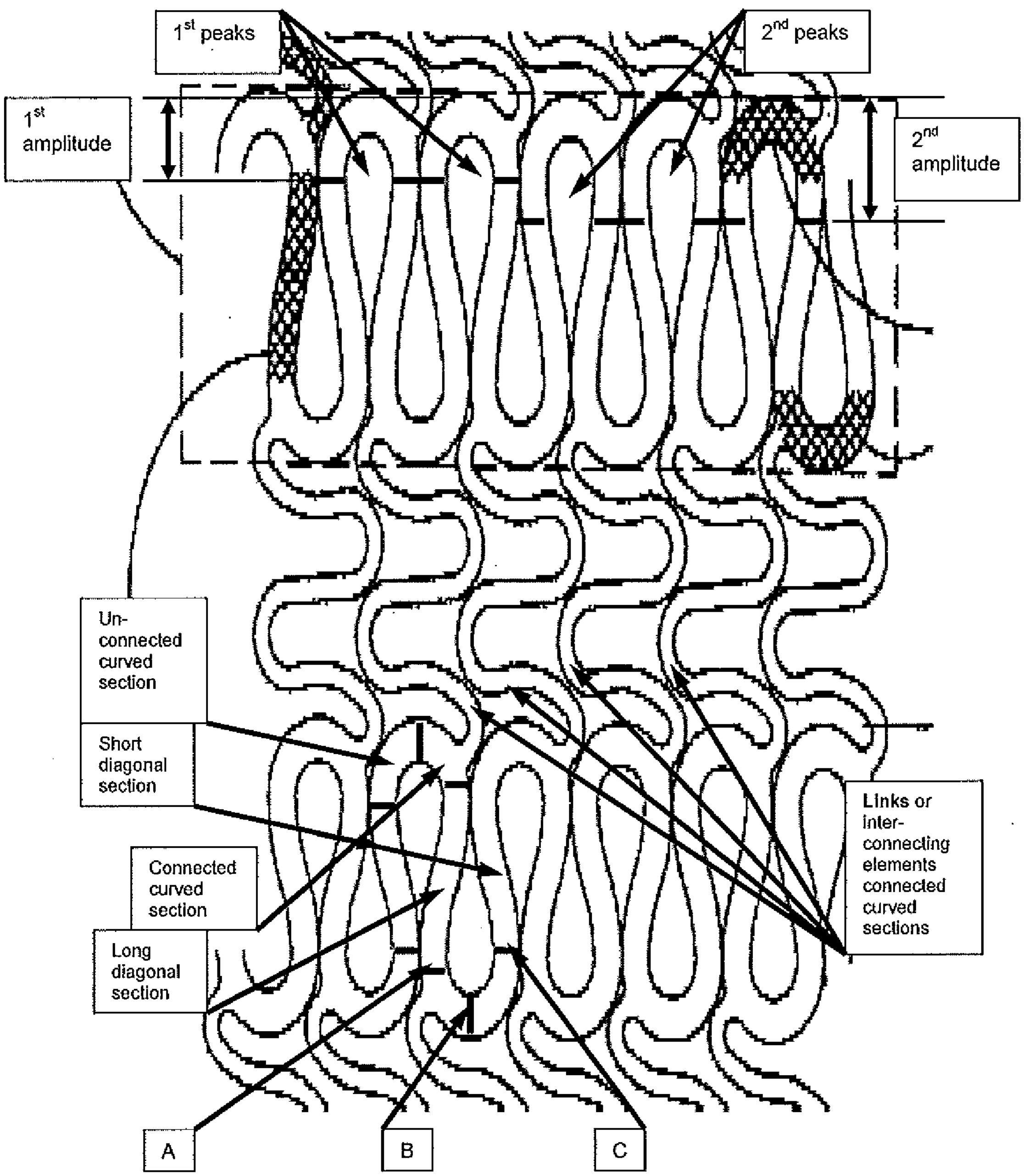
In rejecting claim 38 over Fischell, the Examiner provides annotated figure 9 of Fischell, shown below, and asserts:

> Notice that the limitation "short diagonal section", "long diagonal section", "unconnected curved section", "connected curved section", "peaks", and so on in the claims are broadly interpreted. Therefore, partial of Fischell-'403's Fig. 9 reproduced below shows . . . short diagonal sections, long diagonal sections, unconnected curved sections and connected curved sections to define connected strut members and unconnected strut members substantially as recited in the claims.

Final Office Action, page 2, numbered paragraph 1.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Moreover, as stated in MPEP § 2111 and *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005), "[t]he Patent and Trademark Office ("PTO") determines the scope of claims in patent applications, not solely on the basis of the claim language, but upon giving

claims their broadest reasonable construction '<u>in light of the specification as it would be interpreted by one of ordinary skill in the art.</u>'" (Emphasis added) (internal citations omitted). Fischell does not disclose each and every claimed element of the instant claims. In addition, one of ordinary skill in the art would not interpret the claimed subject matter in a manner consistent with the Examiner's characterization of Fischell as presented in the office action:



Fischell does not disclose unconnected curved sections of an interior circumferential set. Referring to fig. 9 of Fischell, shown below (in un-annotated form), Fischell discloses that "[e]very curved end strut 43 of a central set of strut members 42 is attached to either a connecting link which is an sine wave link 44 or a curved "J" link 46." Column 7, lines 47-50 (emphasis added).

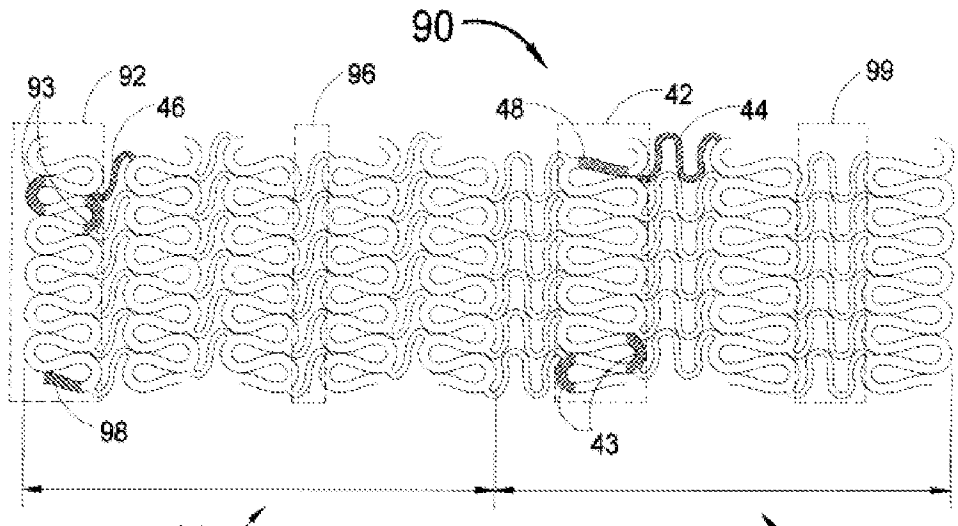


FIG. 9

Thus, each curved end strut of the stent of Fischell is connected to an adjacent curved end strut. Consequently, Fischell does not disclose a stent having unconnected curved sections, as claimed in claim 38 and as shown, for example, in figure 10 of the immediate application, below.

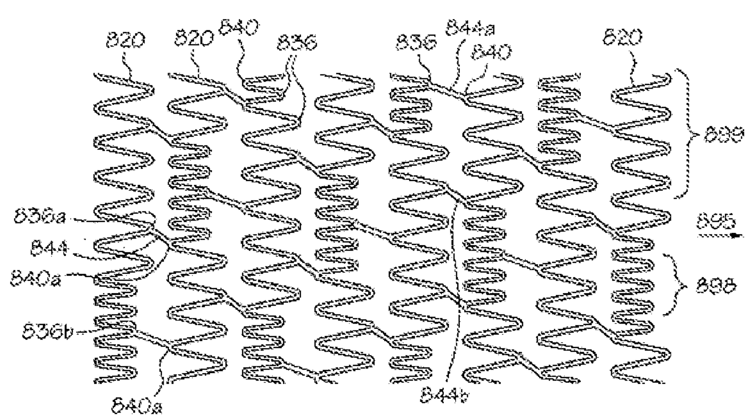


FIG. 10

In addition, the Examiner's annotated figure, *supra*, shows the "curved end struts 43" and "curved diagonal struts 48" of Fischell parsed into seemingly arbitrary sections. The Examiner's interpretation, embodied in the annotated figure, does not comport with the ordinary and customary meaning of the claimed terms. *See* MPEP § 2111.01. For example, a person having ordinary skill in the art would not interpret the seemingly arbitrary portion of the "curved end strut 43" of Fischell as Applicants' claimed "unconnected curved section," especially in light of Applicants' preceding claim language reciting, "each interior circumferential set of strut members including a plurality of strut members connected by curved sections . . . ." In short, Fischell simply does not disclose unconnected curved sections. Fischell, teaches that <u>each</u> end section is connected.

Therefore, Fischell does not disclose each claimed element, and the Examiner's rejection does not amount to a *prima facie* case of anticipation. Thus, Applicants request that the Board reverse the Examiner's rejection of independent claim 38.

With regard to dependent claims 42, 43, and 45, these claims depend from independent claim 38 and are therefore patentable for at least the reasons discussed above with respect to independent claim 38. As such, Applicants request that the Board reverse the Examiner's rejection of dependent claims 42, 43, and 45.

With further regard to dependent claims 42, 43, and 45, Applicants are unable to find any substantive rejection of the subject matter of these claims in the Final Office Action. Applicants therefore assert that the Examiner has failed to comply with the requirements of 37 CFR 1.104(c)(2)("[t]he pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.").

Therefore, Applicants request that the Board reverse the Examiner's rejection of dependent claims 42, 43, and 45 for this additional reason.

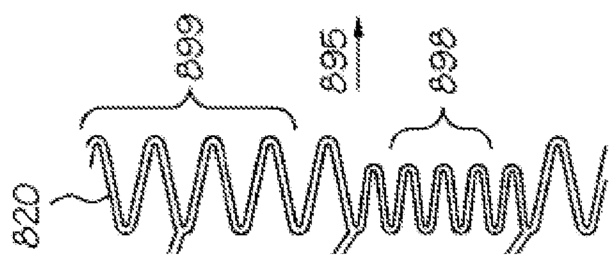
<u>Independent Claim 58 and Dependent Claims 59, 60, and 65</u>

Independent claim 58 recites, in-part, "the peaks of each band-like element comprising peaks of a first amplitude and peaks of a second amplitude, the first amplitude being less than the second amplitude . . . ."

In rejecting independent claim 58, the Examiner again points to annotated figure 9, *supra*, asserting that Fischell discloses the claimed subject matter. The rejection is *traversed*. Fischell does not disclose peaks of different amplitude within a band-like element.

The Examiner's characterization of Fischell does not comport with the plain meaning of the word "amplitude." The Examiner attempts to deconstruct a band of the Fischell stent in such a way that it can be said to have peaks of different amplitudes. One of ordinary skill in the art would recognize that each band of the Fischell stent consists peaks of only one amplitude. The Examiner's deconstruction fails in that it implicitly (and inappropriately) applies multiple inconsistent interpretations to the term "peak."

Moreover, the Examiner's interpretation of the claims is inconsistent with the Specification, contrary to the directions of MPEP section 2111. ("During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.'"). Referring to figure 10 of the immediate Application, shown above, Applicants' Specification recites, "each band-like element 820 is seen to comprise peaks 836 of more than one amplitude and troughs 840 of more than one amplitude, however, peaks of the same amplitude are grouped together within a band-like element as are troughs of the same amplitude." App. A, page 12, lines 3-6. The Specification was contemplating at least fig. 10, which, as shown below, includes a grouping of larger amplitude peaks and another grouping of smaller amplitude peaks.



Using the reasoning of the Examiner, the above segment could not be characterized as having peaks of the same amplitude grouped together since the band could be characterized as having an infinite number of peak amplitudes. This is a consequence of simultaneously (and inappropriately) applying multiple (inconsistent) definitions of the term.

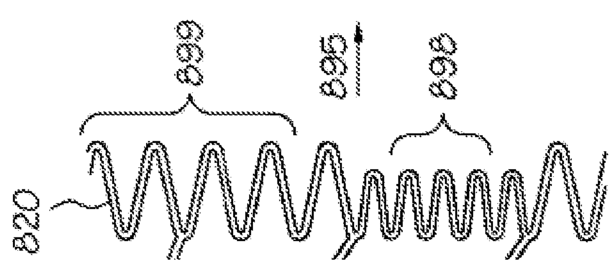
The Specification and figures rule out applying multiple arbitrary definitions of the peak amplitude. Thus, the Examiner's interpretation of the claims is inconsistent with the Specification.

In addition, and without acquiescing to any particular definition, the Examiner's interpretation of the word "amplitude" does not comport with the plain meaning of the word. Amplitude can be defined as "[i]n physics, the height of a crest (or the depth of a trough) of a wave." (emphasis in original) *The American Heritage® New Dictionary of Cultural Literacy*, Third Edition. (Retrieved April 05, 2010, from Dictionary.com website: http://dictionary.reference.com/browse/amplitude). Another definition for amplitude is "[t]he maximum absolute value of a periodic curve measured along its vertical axis." *The American Heritage® Dictionary of the English Language*, Fourth Edition (Retrieved April 05, 2010, from Dictionary.com website: http://dictionary.reference.com/browse/amplitude).

The Examiner's arbitrarily defined "amplitude(s)" does not comport with the plain meaning of the word and one of ordinary skill in the art would recognize that each band of the Fischell stent consists of peaks of only one amplitude.

Therefore, Fischell does not disclose each and every element claimed in independent claim 58 and Applicants request that the Board reverse the Examiner's rejection of independent claim 58 and dependent claims 59, 60, and 65.

With further regard to dependent claim 59, dependent claim 59 recites, in-part, "wherein peaks of the same amplitude are grouped together within a band-like element." *See e.g.*, partial view of figure 10, shown below:



Fischell does not disclose this claimed subject matter. And, as discussed above, Applicants' Specification precludes multiple arbitrary definitions of peak amplitude. As Fischell

fails to disclose the subject matter of claim 59, Applicants request that the Board reverse the Examiner's rejection of dependent claim 59 for this additional reason.

With further regard to dependent claim 60, claim 60 recites, "wherein peaks having the first amplitude on a first band-like element are circumferentially offset from peaks having the first amplitude on a second band-like element." Fischell simply does not disclose such a stent. Consequently, Applicants request that the Board reverse the Examiner's rejection of dependent claim 60 for this additional reason.

With regard to dependent claim 65, this claim depends from claim 64, which is rejected under 35 USC § 103(a) over Fischell. It is unclear how claim 65 can be rejected under 35 USC § 102(e) over Fischell when the claim from which it depends is rejected under 35 USC § 103(a).

Moreover, Fischell does not disclose, teach, suggest, or otherwise render obvious the subject matter of this dependent claim. Claim 65 recites, "wherein interconnecting elements having a first length extend from the peaks having the first amplitude on a band-like element to a trough on an adjacent band-like element."

In light of the foregoing, Applicants request that the Board reverse the Examiner's rejection of dependent claim 65.

Issue 2: The Examiner erred in rejecting claims 39 and 63 under 35 USC § 103(a) over Fischell (US 6,190,403) in view of Kanesaka (US 5,810,872).

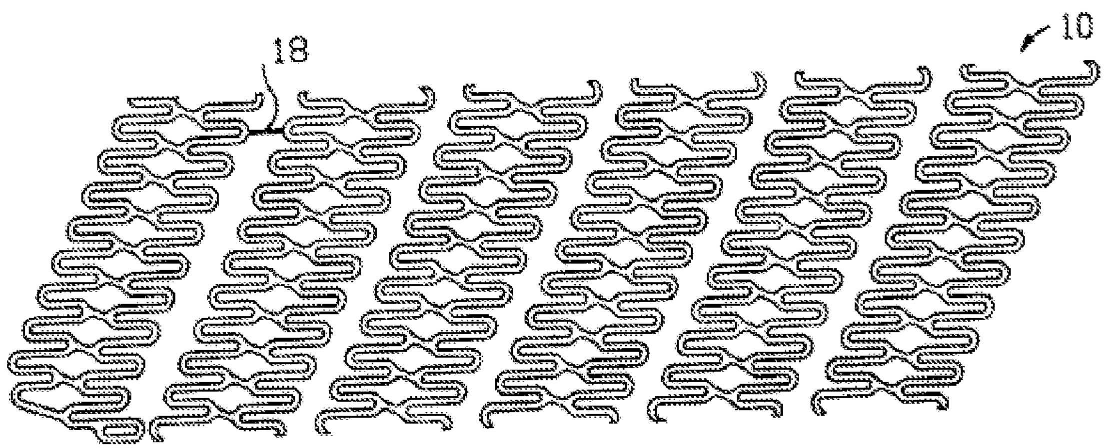
The Examiner's rejections of dependent claims 39 and 63 are *traversed* because Fischell, in view of Kanesaka, does not disclose, teach, suggest, or otherwise render obvious the subject matter of claims 39 and 63.

Dependent claims 39 and 63 depend from independent claims 38 and 58, respectively. Kanesaka does not remedy the deficiencies of Fischall discussed above with respect to independent claims 38 and 58. Therefore, Applicants request that the Board reverse the rejection of dependent claims 39 and 63.

Turning to the claim language of claims 39 and 63, claim 39 recites, "wherein the longitudinal connecting link is straight." Claim 63 recites, "wherein each of the plurality of interconnecting elements is substantially straight."

In rejecting claims 39 and 63 over Fischell in view of Kanesaka, the Examiner asserts, "Kanesaka-872 discloses a stent as shown in Fig. 1 having wavy band connecting [sic] by substantially straight elements. It would have been obvious to one of ordinary skill in the art to provide straight links to a Fischell-'403 stent as straight links are well known links in the stent art." Final Office Action, page 4, numbered paragraph 1. Figure 1 of Kanesaka is provided below for reference.

FIG. 1



Applicants disagree with the Examiner's assertion. One of ordinary skill would not be motivated to the use the "bridge struts 18" of Kanesaka with the stent of Fischell as the Examiner asserts. Fischell teaches that "an object of [the] invention is to have a multi-cell, thick-walled stent with at least two different types of closed perimeter cells where <u>every</u> cell includes at least one longitudinally extending flexible link." Column 1, lines 59-62. Consequently, one of ordinary skill would not be motivated to substitute the alleged "straight link" of Kanesaka to the stent of Fischell. For this additional reason, Applicants request that the Board reverse the Examiner's rejection of dependent claims 39 and 63.

Issue 3: The Examiner erred in rejecting claim 46 under 35 USC § 103(a) over Fischell (US 6,190,403) in view of Anderson (US 5,800,526).

The Examiner's rejection of claim 46 under 35 USC § 103(a) over Fischell in view of Anderson is *traversed*. Dependent claim 46 depends from independent claim 38 and the disclosure of Anderson does not remedy the deficiencies of Fischell as discussed above with respect to independent claim 38. In short, the Examiner has failed to establish a *prima facie* case of obviousness and Fischell in view of Anderson does not teach, suggest, or otherwise render obvious the subject matter of claim 46. Consequently, Applicants request that the Board reverse the Examiner's rejection of dependent claim 46

Issue 4: The Examiner erred in rejecting claims 57, 61, 62, 64, and 66 under 35 USC § 103(a) over Fischell (US 6,190,403).

The Examiner's rejection of dependent claims 57, 61, 62, 64, and 66 under 35 USC § 103(a) over Fischell is *traversed*. In rejecting these dependent claims, the Examiner asserts, "Fischell-'403 discloses substantially all limitations of the claimed invention, except for some minor modifications as recited in the claims. There is no evident [sic] that these modifications will significantly improve the performance of Fischell-'403." Final Office Action, page 4, numbered paragraph 3.

At the outset, Applicants note that the appropriate question under 35 USC § 103 is not whether the differences between the claimed invention and the teachings of the prior art would "significantly improve" the prior art. Instead, the relevant question is whether "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 USC § 103(a).

In this regard, the Examiner has failed to establish a *prima facie* case of obviousness. For example, with respect to claim 61, the Examiner asserts that claim 61 is obvious over Fischell because "Fischell-'403 can be manually locally stretched at different portions of one set of circumferential strut members to have different wavelengths from the

unstretched portions." Final Office Action, page 5, numbered paragraph 3. The Examiner does not cite any part of Fischell for this proposition. In addition, the Examiner has not provided any reason for making the alleged modification. *See* MPEP 2143 (rejections should be made explicit).

In rejecting claim 64, the Examiner merely states, "[a]s to claim 64, 1st length and 2nd length are not clearly defined and a 1st length of 1st interconnecting elements and a 2nd length of 2nd length interconnecting elements can be chosen to meet the limitation of the claim." Final Office Action, page 5, numbered paragraph 3. Applicants disagree. One of ordinary skill in the art would readily understand what is meant by "first interconnecting elements having a first length and second interconnecting elements having a second length, wherein the first length is longer than the second length," as is claimed in claim 64 and shown, below, with reference numerals 844a and 844b of figure 10 of the immediate Application. *See also* app. A, page 12, line 29-page 13, line 2.

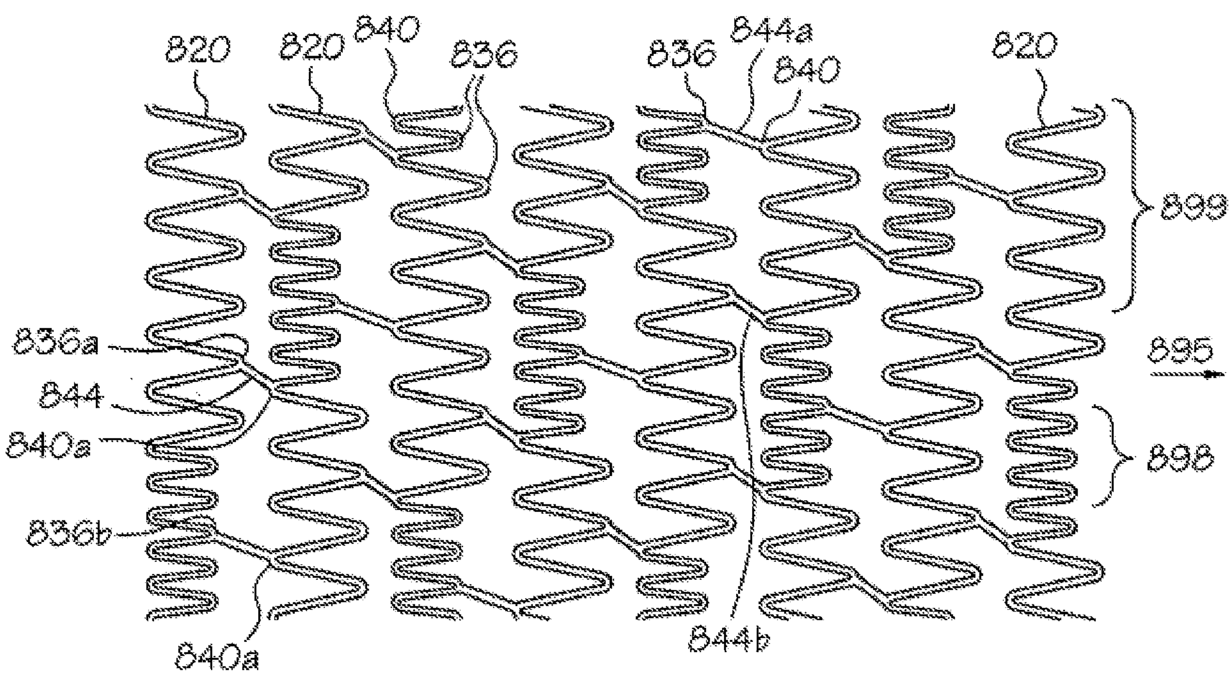


FIG. 10

Therefore, the Examiner's assertion – that the "1st length and 2nd length are not clearly defined" – is erroneous, and the rejection of claim 44 fails to establish a *prima facie* case of obviousness.

With regard to dependent claim 66, claim 66 recites, "wherein the peaks of the second amplitude extend further toward the first end of the stent than the peaks of the first amplitude." In rejecting this claim over Fischell, the Examiner asserts, "[i]t would be reasonable for one of ordinary skill in the art to conclude that 2nd peaks extend further toward the 1st end than 1st peaks because 2nd peaks are longer than 1st peaks." Final Office Action, page 5, numbered paragraph 5. Applicants wholly disagree. Nothing in Fischell indicates that the alleged "peaks" of Fischell extend beyond any other peaks of a particular band-like element. *See e.g.*, figure 9 of Fischell, *supra*.

In light of the foregoing, Applicants request that the Board reverse the Examiner's rejections of dependent claims 61, 64, and 66 for the attritional reasons discussed above. The Examiner's rejections of the dependent claims is insufficient to establish a *prima facie* case of obviousness under 35 USC § 103(a).

<u>Issue 5: The Examiner erred in rejecting claims 67-70 under 35 USC § 102(e) over Al-Saadon (US 5,755,776).</u>

The Examiner's rejections of claims 67-70 are *traversed* because Al-Saadon does not disclose the subject matter of independent claim 67. Independent claim 67 recites, in-part, "adjacent struts members within an interior set arranged in pairs of strut members wherein some of the strut pairs including a longer strut member and a shorter strut member. . . ."

In rejecting this claim over Al-Saadon, the Examiner provided the following annotated figure (FIG. 7) from Al-Saadon.

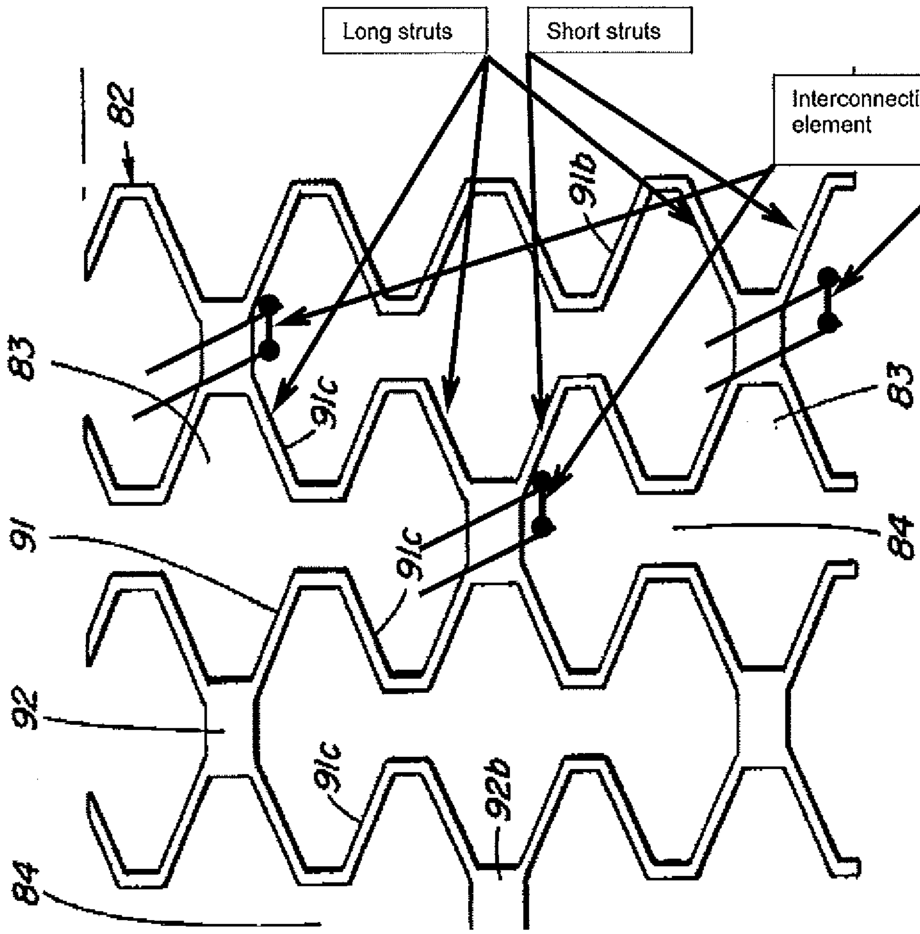


FIG. 7

In rejecting claims 67-70 under 35 USC § 102(e), the Examiner asserts, "Al-Saadon-'776 (F7) discloses substantially all the limitations of the claimed invention, such as long struts, short struts, interconnecting elements. Please, notice that the claims do not have any limitation to clearly define a strut (where does it start and end?) or an interconnecting elements (where does it start and end?)." Final Office Action, page 6. Applicants disagree with the Examiner's assertions.

Although Al-Saadon discloses that the "elongate members 91 of tubular stent 120 [of FIGS. 4 and 5] are more elongatable than those of tubular stent 80 of FIGS. 1 and 2," column 3, lines 52-53, Applicants are unable to find anything in the disclosure of Al-Saadon that discloses "strut pairs including a longer strut member and a shorter strut member," as is claimed. Moreover, as shown in FIG. 7 of Al-Saadon, the elongate members 91 all appear to be the same length.

Furthermore, the Examiner's characterization of Al-Saadon as allegedly having "short struts" and "long struts" applies an arbitrary length to the elongate member(s) 91 by including a portion of the connecting member(s) 92. One of ordinary skill in the art would not characterize Al-Saadon or Applicants' claims as the Examiner has. By way of example, Al-Saddon recognizes a distinction between the "connecting member" and the "elongate member"; Al-Saddon identifies the "connecting member" by reference numeral 92 and the "elongate member" by reference numeral 91.

In addition, the Examiner's characterization ascribes a meaning to the immediate claim language that is inconsistent with the plain meaning of the claim terms. One of ordinary skill in the art would recognize that the claimed shorter and longer strut members <u>do not</u> include portions of the interconnecting elements. Indeed, the claimed interconnecting elements are shown, for example, at reference numeral 844, connecting "peaks 836 and troughs 840 in adjacent band-like elements 820." App. A, page 12, lines 9-10.

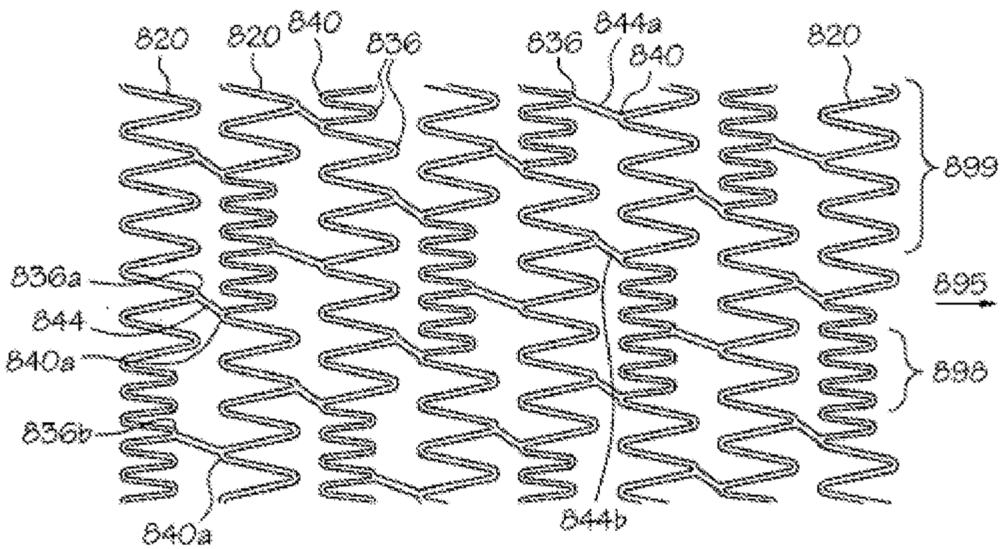


FIG. 10

In sum, Al-Saadon does not disclose "strut pairs including a longer strut member and a shorter strut member," as is claimed. The Examiner's characterization of Al-Saadon is inconsistent with the disclosure of Al-Saadon, inconsistent with Applicants' Specification, and inconsistent with the plain meaning of the claim terms.

With regard to the Examiner's assertion – that "Al-Saadon-'776 (F7) discloses substantially all of the limitations of the claimed invention . . . ," Applicants note that a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Examiner's assertion that Al-Saadon discloses "substantially all of the limitations" is insufficient to reject claims under 35 USC § 102(e) as being anticipated. In light of the foregoing, Applicants request that the Board reverse the Examiner's rejection of claim 67 and claims 68-70 depending therefrom.

With further regard to dependent claims 68-70, nothing in Al-Saadon discloses the subject matter of these dependent claims. Dependent claim 68 recites, "wherein some of the interconnecting members extend from strut pairs having a longer strut member and a shorter strut member." Al-Saadon does not disclose such a stent. Dependent claim 69 recites, "wherein the first and second ends of each interconnecting member are circumferentially and longitudinally offset from one another." Al-Saadon simply does not disclose the elements of this claim. Dependent claim 70 recites, "wherein said pathway includes two strut members of one length and one strut member of a different length." Finally, Al-Saadon does not disclose the elements of claim 70, either.

Moreover, with regard to dependent claims 68-70, the Examiner has failed to comply with the requirements of 37 CFR 1.104(c)(2)("[t]he pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified."). It is unclear how it is believed that the Al-Saadon discloses the subject matter of (at least) dependent claims 68-70.

For at least the foregoing reasons, the Examiner has failed to establish a *prima facie* case of anticipation. Consequently, Applicants request that the Board reverse the Examiner's rejection of independent claim 67 and dependent claims 68-70.

Conclusion

Based on at least the foregoing arguments, Applicants respectfully submit that the rejections presented by the Examiner fail to anticipate or render obvious Applicants' claims. Accordingly, Applicants respectfully request that the Board reverse the Examiner's rejections

Respectfully submitted,

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(viii) Claims Appendix

38. A stent in the form of a thin-walled, cylindrical tube with a longitudinal axis, the stent comprising:

a multiplicity of interior circumferential sets of strut members and one end circumferential set of strut members at each of the two longitudinal ends of the stent, each interior circumferential set of strut members and each end circumferential set of strut members having a first end and a second end;

each interior circumferential set of strut members including a plurality of strut members connected by curved sections, the curved sections located at the first and second ends, the curved sections including connected curved sections and unconnected curved sections, each two adjacent strut members connected by a single curved section,

the strut members including at least one connected strut member consisting of a long diagonal section having a longitudinal length fixedly attached to a connected curved section,

each connected curved section being joined by means of a longitudinal connecting link to one connected curved section of an adjacent circumferential set of strut members, all connecting links that connect adjacent circumferential sets of strut members connected at a connected curved section,

the strut members also including at least one unconnected strut member consisting of a short diagonal section having a longitudinal length fixedly joined to an unconnected curved section.

39. The stent of claim 38 wherein the longitudinal connecting link is straight.

42. The stent of claim 38 wherein there are three longitudinal connecting links that join each adjacent pair of circumferential sets of strut members.

43. The stent of claim 38 wherein there are five longitudinal connecting links that join each adjacent pair of circumferential sets of strut members.

45. The stent of claim 38 wherein the metal from which the stent is formed in stainless steel.

46. The stent of claim 38 wherein the metal from which the stent is formed is tantalum.

57. The stent of claim 38, wherein each interior circumferential set of strut members has fewer connected curved sections than unconnected curved sections.

58. A cylindrical expandable stent comprising:

a plurality of undulating band-like elements aligned on a common longitudinal axis to define a generally tubular stent body having a first end and a second end, each band-like element having alternating peaks and troughs, the peaks and troughs taking a generally longitudinal direction along the cylinder,

the peaks of each band-like element comprising peaks of a first amplitude and peaks of a second amplitude, the first amplitude being less than the second amplitude; and

a plurality of interconnecting elements, each interconnecting element having a first end and a second end, the first and second ends extending from adjacent band-like elements, the first and second ends displaced circumferentially along the stent.

59. The stent of claim 58, wherein peaks of the same amplitude are grouped together within a band-like element.

60. The stent of claim 59, wherein peaks having the first amplitude on a first band-like element are circumferentially offset from peaks having the first amplitude on a second band-like element.

61. The stent of claim 58, wherein each of the plurality of band-like elements has a first region having a first wavelength and a second region having a second wavelength, wherein the first wavelength is less than the second wavelength.

62. The stent of claim 61, wherein the first region comprises peaks having the first amplitude.

63. The stent of claim 58 wherein each of the plurality of interconnecting elements is substantially straight.

64. The stent of claim 58, wherein the plurality of interconnecting elements is comprised of first interconnecting elements having a first length and second interconnecting elements having a second length, wherein the first length is longer than the second length.

65. The stent of claim 64, wherein interconnecting elements having a first length extend from the peaks having the first amplitude on a band-like element to a trough on an adjacent band-like element.

66. The stent of claim 58 wherein the peaks of the second amplitude extend further toward the first end of the stent than the peaks of the first amplitude.

67. A stent comprising:

a multiplicity of interior sets of strut members, each interior set having a first end and a second end and a plurality of strut members which are connected one to the other, adjacent struts members within an interior set arranged in pairs of strut members wherein some of the strut pairs including a longer strut member and a shorter strut member, adjacent interior sets connected to one another via interconnecting elements,

wherein the interconnecting elements are arranged such that each interconnecting element which connects to an interior set adjacent its first end is connected to an interconnecting element which connects to an interior set adjacent its second end via a pathway of only three connected strut members of the interior set.

68. The stent of claim 67 wherein some of the interconnecting members extend from strut pairs having a longer strut member and a shorter strut member.

69. The stent of claim 68 wherein the first and second ends of each interconnecting member are circumferentially and longitudinally offset from one another.

70. The stent of claim 67 wherein said pathway includes two strut members of one length and one strut member of a different length.

(ix) Evidence Appendix

Appendix A – Application as Filed on November 10, 2003.

Appendix B – Preliminary Amendment as filed on November 10, 2003.

(x) Related Proceedings Appendix

Decision from BPAI for Application No. 08/511,076 mailed on Sept. 25, 2001

Appendix A – Application As-Filed on November 10, 2003

IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

This application is a Continuation-in-Part of application Serial No. 08/511,076, filed August 3, 1995, the disclosure of which is hereby incorporated by reference.

Field of the Invention

This invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel. More specifically, it relates to a tubular expandable stent of improved longitudinal flexibility.

Background of the Invention

Stents are placed or implanted within a blood vessel for treating stenoses, strictures or aneurysms therein. They are implanted to reinforce collapsing, partially occluded, weakened, or dilated sections of a blood vessel. They have also been implanted in the urinary tract and in bile ducts.

Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding and some are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon.

An example of the latter type is shown in U.S. Patent No. 4,733,665 to Palmaz, which issued March 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

A type of self-expanding stent is described in U.S. Patent No. 4,503,569 to Dotter which issued March 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Other types of self-expanding stents not made of shape memory material are also known.

This invention is directed to stents of all these types when configured so as to be longitudinally flexible as described in detail hereinbelow. Flexibility is a desirable feature in a stent so as to conform to bends in a vessel. Such stents are known in the prior art. Examples are shown in U.S. Patent No. 4,856,516 to Hillstead; U.S.

Patent No. 5,104,404 to Wolff; U.S. Patent No. 4,994,071 to MacGregor; U.S. Patent No. 5,102,417 to Palmaz; U.S. Patent No. 5,195,984 to Schatz; U.S. Patent No. 5,135,536 to Hillstead; U.S. Patent 5,354,309 to Shepp-Pesch et al.; EPO Patent Application 0 540 290 A2 to Lau; EPO Patent Application No. 0 364 787 B1 to Schatz, and PCT Application WO 94/17754 (also identified as German Patent Application 43 03 181).

Generally speaking, these kinds of stents are articulated and are usually formed of a plurality of aligned, expandable, relatively inflexible, circular segments which are interconnected by flexible elements to form a generally tubular body which is capable of a degree of articulation or bending. Unfortunately, a problem with such stents is that binding, overlapping or interference can occur between adjacent segments on the inside of a bend due to the segments moving toward each other and into contact or on the outside of a bend the segments can move away from each other, leaving large gaps. This can lead to improper vessel support, vessel trauma, flow disturbance, kinking, balloon burst during expansion, and difficult recross for devices to be installed through already implanted devices and to unsupported regions of vessel.

A diamond configuration with diagonal connections between each and every diamond of each segment is also known but such closed configurations lack flexibility.

It is an object of this invention to provide a longitudinally flexible stent of open configuration that avoids these problems and exhibits improved flexibility (radially and longitudinally) in the stent body segments thereof rather than in flexible joints between the segments.

It is a further object of the present invention to provide a stent that is flexible yet also allows for side branch access.

Summary of the Invention

It is a goal of the present invention to provide a flexible stent formed of interconnected bands which provides for side branch access and which further avoids the problem of pinching or overlap between adjacent bands. Pinching or overlap is avoided where peaks and troughs of adjacent bands are circumferentially displaced relative to each other. The stents of the present invention accomplish this goal by having different bands characterized by different wavelengths over the length of the

stent and/or disposing the interconnecting members in such a way that after expansion of the stent, the phase relationship between adjacent bands is altered with the peaks and troughs displaced circumferentially relative to each other.

The inventive expandable stents are formed of a plurality of interconnected band-like elements characterized by alternating peaks and troughs. The ends of the interconnecting members which join adjacent bands are circumferentially offset and optionally, longitudinally offset. Peaks and troughs in adjacent bands are circumferentially offset as well so that the stent, in an expanded state, will have minimal overlap of peaks and troughs.

To this end, the invention provides a tubular, flexible, expandable stent, comprising a plurality of undulating band-like elements of a selected wavelength or wavelengths. The band-like elements have peaks and troughs and are aligned on a common longitudinal axis to define a generally tubular stent body. The peaks and troughs take a generally longitudinal direction along the stent body. Adjacent band-like elements may be in phase or out of phase with each other. The inventive stents further comprise a plurality of interconnecting elements having first ends and second ends. The first and second ends extend from adjacent band-like elements and are displaced from one another in a longitudinal direction and in a radial direction along the stent. Desirably, upon expansion of the stent, at least some of the peaks and troughs of a given band-like element are displaced relative to each other about the periphery of the stent to accommodate longitudinal flexing of the stent within the band-like elements and without interference between adjacent band-like elements.

In one embodiment, two different types of band-like elements are present in the stent, first band-like elements with a first selected wavelength and second band-like elements with a second selected wavelength exceeding the first selected wavelength. The first and second band-like elements preferably alternate over the length of the stent. Although the terminology of 'first band-like element' and 'second band-like element' is used, it is not intended to convey the relative order of appearance of the elements in the inventive stents.

In another embodiment, two different types of band-like elements are present, first and second band-like elements, each of which has peaks and troughs. The first band-like elements have more peaks (or troughs) than the second band-like elements. Similarly, the invention is also directed to embodiments having first and

second band-like elements with peaks and troughs where the peaks (or troughs) of the first band-like elements are spaced closer together than the peaks (or troughs) of the second band-like elements.

In another embodiment in which band-like elements of only one wavelength are present, adjacent bands are about 180° out of phase with one another. Interconnecting elements extend at an oblique angle relative to the longitudinal axis from a peak to a trough on an adjacent band.

In another embodiment in which band-like elements of only one wavelength are present, peaks from which interconnecting elements emanate are elongated relative to the peaks which are not connected to troughs and similarly, the troughs from which interconnectors emanate are elongated relative to troughs which are not connected to peaks. Further, each interconnecting element extends from the side of a peak to the side of a trough on an adjacent band.

In yet another embodiment in which band-like elements of only one wavelength are present, adjacent bands are about 90° out of phase with one another. Each interconnecting element extends between a peak and a trough and the ends of the interconnecting member are circumferentially offset from one another and, optionally, longitudinally offset.

The invention further provides a tubular, flexible, expandable stent having a longitudinal axis, comprising one or more cylindrical shaped first segments having first struts, the first segment being defined by a member formed in an undulating pattern of interconnected paired first struts and in which adjacent pairs of first struts in a given first segment are interconnected at opposite ends and one or more cylindrical shaped second segments defined by a member formed in an undulating pattern of interconnected paired second struts and in which adjacent pairs of second struts in a given second segment are interconnected at opposite ends. The first struts are shorter than the second struts. The first segments are formed of a number of first struts and the second segments are formed of a number of second struts with the number of first struts in a first segment exceeding the number of second struts in a second segment. The first and second segments, present and desirably alternating along the stent body, are aligned on a common longitudinal axis to define a generally tubular stent body. Adjacent first and second segments are connected by a plurality of interconnecting elements, each interconnecting element extending from an end of paired first struts on a first segment to

an end of paired second struts on an adjacent second segment. The ends of interconnecting elements are circumferentially offset relative to each other, and optionally, longitudinally offset. Desirably, upon expansion of the stent, the paired struts of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

Brief Description of the Figures

Figure 1a shows a band-like element used in the inventive stents.

Figure 1b shows a schematic of a peak region which contains a double peak and a trough region containing a double trough.

Figure 2 shows a flat view of a stent configuration according to the invention.

Figure 3 shows the pattern of Figure 2 in a tubular stent.

Figure 4a shows a flat view of a stent configuration according to the invention.

Figure 4b shows a flat view of a stent configuration according to the invention.

Figure 5a shows a flat view of a stent configuration according to the invention.

Figure 5b shows a flat view of a stent configuration according to the invention.

Figure 6 shows a flat view of a stent configuration according to the invention.

Figure 7 shows a flat view of a stent configuration according to the invention.

Figure 8 shows a flat view of a stent configuration according to the invention.

Figure 9 shows a flat view of a stent configuration according to the invention.

Figure 10 shows a flat view of a stent configuration according to the invention.

Figure 11 shows a flat view of a stent configuration according to the invention.

Figure 12 shows a flat view of a stent configuration according to the invention.

Figure 13 shows the pattern of Figure 12 in a tubular stent.

Figure 14 shows an expanded stent of the configuration shown in Figure 12.

Figure 15 shows a flat view of an alternate stent configuration according to the invention.

Detailed Description of the Invention

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

For the sake of consistency, the terms 'peak' and 'trough' shall be defined with respect to the proximal and distal ends of the stent. Each of the stents has a proximal end 91 and a distal end 93 and a longitudinal axis 95, as seen in Fig. 1a. Peaks 36 are generally concave relative to the proximal end of the stent and generally convex relative to the distal end of the stent. Troughs 40, on the other hand, are generally convex relative to the proximal end of the stent and generally concave relative to the distal end of the stent. Notwithstanding this definition, the term peak is also intended to extend to regions 48 that are generally peak-like which may, nevertheless, contain trough-like regions within the peak-like region as seen in Fig. 1b. Similarly the term trough is also intended to extend to regions 52 that are generally trough-like which may, nevertheless, contain peak-like regions within the trough-like region as seen in Fig. 1b.

Corresponding to each peak 36 is an inner diameter peak 38 where the inner diameter of the band-like element reaches its peak. The set of points on a given band-like element which are distal to inner diameter peak 38 is denoted peak region 48. Similarly, corresponding to each trough 40 is an inner diameter trough 42 where the inner diameter of the band-like element reaches its trough. The set of points on a given band-like element which are proximal to inner diameter trough 42 is denoted trough region 52. For the sake of clarity, unless otherwise indicated, analogous portions of

stents will be similarly labeled, using three digit reference numerals to distinguish among the various embodiments shown.

Also included within this definition of peak regions and trough regions are peak regions which are comprised of multiple peaks as well as trough regions which are comprised of multiple troughs such as those shown schematically in Fig 1b. Peak 36 is seen to consist of two sub-peaks 36a,b and trough 40 is similarly seen to consist of two sub-troughs 40a,b. In the case of peaks containing sub-peak and troughs containing sub-troughs, the peak region 48 includes all of the points along the band-like element between the sub-peaks that make up the peak and similarly, the trough region 52 includes all of the points along the band-like element between the sub-troughs that make up the trough.

The inventive stents may incorporate one or more bands of a chosen wavelength. In some embodiments, the inventive stents include one or more small amplitude, short wavelength bands to provide for flexibility and one or more large amplitude, long wavelength bands to give side branch access or to provide for sections of alternative strengths such as soft and/or stiff sections.

Turning to the Figures, Figure 2 shows a flat view of a stent configuration and Figure 3 shows the stent of Figure 2 in tubular form. That is, the stent is shown for clarity in Figure 2 in the flat and may be made from a flat pattern 110 (Figure 2) which is formed into a tubular shape by rolling the pattern so as to bring edges 112 and 114 together (Figure 2). The edges may then joined as by welding or the like to provide a cylindrical configuration such as that shown generally at 115 in Figure 3.

A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configuration. It may also be chemically etched or EDM'd (electrical discharge machined) to form an appropriate configuration.

The configuration can be seen in these Figures to be made up of one or more spaced first band-like elements 120. First band-like elements have a generally serpentine configuration to provide continuous waves to the first band-like elements. The waves are characterized by a plurality of peaks 124 and troughs 128 taking a generally longitudinal direction along the cylinder such that the waves in first band-like elements 120 open as the stent is expanded from an unexpanded state having a first diameter to an expanded state having a second diameter.

The stent further comprises a plurality of spaced second band-like elements 132 having a generally serpentine configuration to provide continuous waves to the second band-like elements. The waves are characterized by a plurality of peaks 136 and troughs 140 taking a generally longitudinal direction along the cylinder such that the waves in the second band-like elements open as the stent is expanded from an unexpanded state having a first diameter to an expanded state having a second diameter. First and second band-like elements are characterized by respective wavelengths and amplitudes with the wavelength and amplitude of the second band-like elements exceeding the wavelength and amplitude of the first band-like elements.

Adjacent first band-like elements 120 and second band-like elements 132 are interconnected via a plurality of interconnecting elements 144. The ends of interconnecting element are circumferentially offset from each other.

In an embodiment, as shown in Figs. 2 and 3, first band-like elements 120 and second band-like elements 132 alternate over the length of the stent. Optionally, as shown in Figs. 2 and 3, each end 152 of the stent may terminate in a first band-like element. The invention also, however, contemplates each end terminating in a second band-like element, or further, one end terminating in a first band-like element and the other end terminating in a second band-like element.

While a minimum of one connecting element is required to join adjacent band-like elements, two or more interconnecting elements are preferred. In one embodiment, as shown in Figs. 2 and 3, adjacent first and second band-like elements 120 and 132 are connected with three interconnecting elements 144. Further, in one embodiment, adjacent interconnecting elements 144 extending from peaks 136 on a first band-like element 120 are spaced five peaks apart on the first band-like element while adjacent interconnecting elements 144 extending from troughs 140 on a second band-like element 132 are spaced three troughs apart on the second band-like element.

It is a further feature of the present invention that peaks 124 on first band-like elements 120 are circumferentially displaced on the periphery of the stent from troughs 140 on adjacent second band-like elements 132. It is desirable that peaks and troughs be displaced in the expanded state of the stent to minimize the possibility of pinching or overlap between adjacent band-like elements.

Although the stent of Fig. 2 is comprised of two different wavelength band-like elements, the invention contemplates stents with a plurality of different

wavelength band-like elements. As such, other stents may have three, four or more different wavelength band-like elements.

In another embodiment, the inventive stent is comprised of band-like elements of a single wavelength, interconnected by interconnecting elements. Turning to Figs. 4a and 4b, band-like elements 220a,b are interconnected by interconnecting elements 244a,b. Adjacent band-like elements 220a,b are 180° out of phase with one another. In the compressed state, the band-like elements consist of a plurality of peaks 236a,b and troughs 240a,b. Peak region 248a,b and trough region 252a,b have been shaded in one instance for illustrative purposes.

In the embodiment shown in Fig. 4a, each interconnecting element 244a extends between a peak region 248a and a trough region 252a. Rectilinear interconnecting elements 244a consist of a first shank 280a, a second shank 284a and a link 288a disposed in-between the first and second shanks 280a and 284a. First shank 280a extends in a longitudinal direction from peak region 248a and is substantially perpendicular to link 288a. Second shank 284a extends in a longitudinal direction from trough region 252a and is perpendicular to link 288a.

In the embodiment shown in Fig. 4b, the stent differs from the embodiment of Fig. 4a in that interconnecting element 244b extending between a peak region 248b and a trough region 252b is curvilinear rather than rectilinear.

In both figures 4a and 4b, the interconnecting elements are seen to emanate from the middle of the peak and trough regions.

In another embodiment, as shown in Fig. 5a, the inventive stent is comprised of band-like elements 320a of a single wavelength, interconnected by interconnecting elements 344a. Adjacent band-like elements 320a are 180° out of phase with one another. The band-like elements consist of a plurality of peaks 336a and troughs 340a. Interconnecting elements 344a extend between a peak region 348a and a trough region 352a. The peak regions 348a and trough regions 352a from which interconnecting elements 344a emanate on a given band-like element 320a are seen to extend longitudinally beyond adjacent peak regions 348a' and trough regions 352a' from which no interconnecting elements extend. The extension is such that at least a portion of peak regions 348a overlap longitudinally along the stent with at least a portion of trough region 352a on an adjacent band-like element 320a'. Of course, the overlap is limited to the longitudinal direction and not to the circumferential direction.

In another embodiment, as shown in Fig. 5b, interconnecting elements 344b extend between peak region 348b and a second closest trough region 352b on an adjacent band-like element. Interconnecting elements 344b are seen to be perpendicular to the longitudinal axis. As in the stent of Fig. 5a, peak regions 348b from which interconnecting elements 344b extend and trough regions 352b from which interconnecting elements 344b extend may extend beyond adjacent peak regions 348b' and trough regions 352b' from which no interconnecting elements 344b emanates.

In another embodiment, as shown in Fig. 6, adjacent band-like elements 420 are in phase with each other. As in previous Figs, band-like elements 420 are of a single wavelength, interconnected by interconnecting elements 444. The band-like elements consist of a plurality of peaks 436 and troughs 440. Interconnecting elements 444 extend at an oblique angle relative to the longitudinal axis of the stent between a peak region 448 and a trough region 452. As such, ends of interconnecting elements 444 are circumferentially offset relative to each other. The exact angle will, of course, depend on the region from which the interconnecting elements extend, as well as on whether interconnecting elements interconnect nearest peaks and troughs, next nearest peaks and troughs or peaks and troughs that are further separated.

In Figures 5a, 5b and 6, the interconnecting elements are seen to emanate from the sides of the peak and trough regions.

Although for the embodiments of Figs. 1-6, the interconnecting elements extend from peak regions on band-like elements to trough regions on adjacent band-like elements, the invention further contemplates interconnecting elements extending from a position between a peak region and an adjacent trough region on a band-like element to a position intermediate a trough region and a peak region on an adjacent second band-like element as in Fig. 7.

In the embodiment of Fig. 7, interconnecting elements are seen to extend from a region between the peak region and the trough region on a band-like element. The stent is formed of adjacent band-like elements 520 which are 180° degrees out of phase with one another. Interconnecting elements 544 extend from a region intermediate a peak region 548 and a trough region 552 on a band-like element to a region intermediate a peak region 548 and a trough region 552 on an adjacent band-like element. Interconnecting elements 544 consist of a first shank 560, a second shank 564, and an intermediate member 568 disposed in-between first and second shanks 560 and

564. First shank 560 and second shank 564 are substantially perpendicular to intermediate member 568 which extends in the longitudinal direction. Although not depicted, the region from which interconnecting elements 544 emanate may be midway between peaks and troughs.

The embodiment of Fig. 7 also differs from the embodiments of Figs. 2-6 in the orientation of the interconnecting elements. Whereas the interconnecting elements in Figs. 2-6 are all similarly oriented, in the embodiment of Fig. 7, the orientation of interconnecting elements alternates between adjacent pairs of adjacent band-like elements. Specifically, second shanks 564' of interconnecting elements 544' are seen to be displaced in a clockwise circumferential direction along the stent relative to first shanks 560', and seconds shank 564" of interconnecting elements 544" are seen to be displaced in a counterclockwise circumferential direction along the stent relative to while first shank 560".

This feature is also seen in the embodiment of Fig. 8 in which adjacent in-phase band-like elements 620 are interconnected by interconnecting elements 644. Interconnecting elements 644 extend at an oblique angle relative to the longitudinal axis of the stent between a peak region 648 and a trough region 652. As in Fig. 7, the orientation of interconnecting elements alternates between adjacent pairs of adjacent band-like elements. Specifically, the distal ends of interconnecting elements 644' are seen to be oriented in a counterclockwise circumferential direction along the stent relative to the proximal end of the interconnecting elements while the distal ends of interconnecting elements 644" are seen to be displaced in a clockwise circumferential direction along the stent relative to the proximal ends.

Although in the embodiments of Figs 2-8, adjacent bands are connected by five interconnecting elements, additional or fewer interconnecting elements may be used. Further, while interconnecting elements are shown spaced three peaks apart and three troughs apart, other separations are contemplated as well.

In the embodiment of Figure 9, each band-like element 720 is seen to comprise peaks 736 of more than one amplitude and troughs 740 of more than one amplitude . Large amplitude peaks 736a and small amplitude peaks 736b alternate as do large amplitude troughs 740a and small amplitude troughs 740b. As in the previous embodiments, the interconnecting elements are oriented at an oblique angle relative to

the longitudinal axis 795 of the stent. More generally, the invention is directed at stents comprising band-like elements whose amplitude varies along the band-like element.

In another embodiment of the invention, as shown in Fig. 10, each band-like element 820 is seen to comprise peaks 836 of more than one amplitude and troughs 840 of more than one amplitude, however, peaks of the same amplitude are grouped together within a band-like element as are troughs of the same amplitude. It is further noted that in the embodiment of Figure 10, the location of a group of peaks of given amplitude in a band-like element varies circumferentially along the length of the stent. Interconnecting elements 844 connect peaks 836 and troughs 840 in adjacent band-like elements 820. Where several peaks of different amplitudes are present in a band-like element, the invention further contemplates the possibility of interconnecting elements extending from the large peaks 836a to large troughs 840a as in Fig. 9 as well as the possibility of interconnecting elements extending from large peaks to small troughs or from small peaks 836b to large troughs 840a as in Fig. 10. Further, the interconnecting elements between any two adjacent band-like elements may be of different lengths from one another as seen in Fig. 10 and commence at different longitudinal positions within a band-like element and terminate at different longitudinal positions within a band-like element. Interconnecting element 844a is seen to be longer than interconnecting element 844b. As in the previous embodiments, the interconnecting elements are oriented at an oblique angle relative to the longitudinal axis 895 of the stent. In the embodiment of Fig. 10, interconnecting element 844a is seen to be oriented at a smaller oblique angle relative to the longitudinal axis of the stent than interconnecting element 844b. As is apparent from Fig. 10, the invention is also directed to stents comprised of band-like elements whose wavelength varies along a given band-like element. Region 898 and region 899 of band-like element are characterized by different wavelengths.

It is also noted that in the embodiment of Fig. 10, all of the troughs 840a,b in a given band-like element 820 are aligned longitudinally along the stent and differ only in their circumferential position along the stent.

It is further noted in the embodiment of Fig. 10, the stent comprises a first group of interconnecting elements 844a and a second group of interconnecting elements 844b. The interconnecting elements of the first group are all parallel to one another and disposed at a different oblique angle relative to the longitudinal axis than the members of the second group which are all parallel to one another. As such, the

invention contemplates stents having several different groups of obliquely disposed interconnecting elements where the oblique angle differs from group to group.

In another embodiment of the invention, as shown in Fig. 11, each band-like element 920 is seen to comprise peaks 936a,b of different amplitudes and troughs 940 of different amplitudes, however, peaks of the same amplitude are grouped together within a band-like element as are troughs of the same amplitude. It is further noted that in the embodiment of Figure 11 the location of groups of peaks of given amplitude in a band-like element varies circumferentially along the length of the stent. Interconnecting elements 944 connect large amplitude peaks 936a and small amplitude troughs 940b in adjacent band-like elements 920. Similarly, interconnecting elements 944 also connect small amplitude peaks 936b and large amplitude troughs 940a.

The invention also contemplates stents similar to that shown in Fig. 11 in which interconnecting elements extend from large peaks 936a to large troughs 940a, as in Fig. 9. Similarly, interconnecting elements may extend from small peaks 936b to small troughs 940b.

Further, the interconnecting elements between any two adjacent band-like elements may be of different lengths from one another and disposed at different oblique angles.

As is apparent from Fig. 11, the invention is also directed to stents comprised of band-like elements whose wavelength varies along a given band-like element. Region 998 and region 999 of band-like element 920 are characterized by different wavelengths.

It is also noted that in the embodiment of Fig. 11 the large amplitude portions 999 of band-like element 920 are symmetrically disposed about the center 1001 of the band-like element as are the small amplitude portions 998. The center 1001 of the band-like element is defined as a ring that runs along a path that is midway between the large peaks 936a and large troughs 940a of the band-like element. This feature may also be seen in the embodiment of Fig. 9.

The invention is also directed to a tubular, flexible, expandable stent having a longitudinal axis, comprising one or more cylindrical shaped first segments. Cylindrical shaped first segments 20 as seen in Fig. 1, have first struts 23 having first 25 and second 27 ends. First segments 20 are defined by a member formed in an undulating pattern of interconnected paired first struts 23, in which adjacent pairs of first

struts 29' and 29" in a given first segment 20 are interconnected at opposite ends 31' and 31", respectively. Adjacent segments are interconnected.

The stent may be seen more clearly in Figs. 2-8. As shown, the stent of Fig. 3, in addition to comprising first segments 120 which are defined by an undulating pattern of interconnected paired first struts 123 in which adjacent pairs of first struts 129' and 129" in a given first segment 120 are interconnected at opposite ends 131' and 131", respectively, the stent further comprises one or more cylindrical shaped second segments 132, each second segment being defined by a member formed in an undulating pattern of interconnected paired second struts 135 and in which adjacent pairs of second struts 137' and 137" in a given second segment 132 are interconnected at opposite ends 139' and 139", respectively. First struts 123 are shorter than second struts 135. First segments 120 are formed of a number of first struts 123 and second segments 132 formed of a number of second struts 135, the number of first struts in a first segment exceeding the number of second struts in a second segment. First and second segments 120 and 132 are aligned on a common longitudinal axis 195 to define a generally tubular stent body, shown generally at 115. First and second segments 120 and 132 alternate along the stent body. Adjacent first and second segments 120 and 132 are connected by a plurality of interconnecting elements 144. Each interconnecting element 144 extends from an end 131" of paired first struts on a first segment 120 to an end 139" of paired second struts on an adjacent second segment 132. The ends of interconnecting elements 144 are circumferentially offset relative to each other.

Desirably, upon expansion of stent 115, paired struts 129" and 137" of adjacent segments 120 and 132 are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

In the embodiments as shown in Figs. 4a, b, cylindrical shaped segments 220a,b are formed of interconnected struts 223a,b having first 225 and second 227 ends. Adjacent pairs of struts 229a,b' and 229a,b" in a given segment 220a,b are interconnected at opposite ends 231a,b' and 231a,b", respectively. Adjacent segments are connected by a plurality of interconnecting elements 244a,b. Each interconnecting element 244a,b extends from an end of paired struts 231a,b" on a segment to an end of paired struts 231a,b' on an adjacent segment. First end 245a,b and second end 247a,b of

interconnecting elements 244a,b are seen to be circumferentially displaced along the stent.

Similar structure, denoted by similar reference numerals may be found in the stents of Figs. 5a,b, and 6-8.

In particular, in the embodiment as shown in Fig. 8, cylindrical shaped segments 620 are formed of interconnected struts 623, having first 625 and second 627 ends. Segments 620 are defined by a member formed in an undulating pattern of interconnected paired struts 623 in which adjacent pairs of struts 629' and 629" in a given segment 620 are interconnected at opposite ends 631' and 631", respectively. Segments 620 are aligned on a common longitudinal axis 695 to define a generally tubular stent body. Adjacent segments are connected by a plurality of interconnecting elements 644 (and 644') having first 645 (645') and second 647 (647') ends, each interconnecting element 644 (644') extending from an end of paired struts 631" on a segment to an end of paired struts 631' on an adjacent segment. First end 645 (645') and second end 647 (647") are seen to be circumferentially displaced along the stent.

Additional embodiment of the stents are shown in Figs 12-15. Figure 12 and Figure 13 show a fragmentary flat view of an unexpanded stent configuration and the actual tubular stent (unexpanded), respectively. That is, the stent is shown for clarity in Figure 12 in the flat and may be made from a flat pattern 1110 (Figure 12) which is formed into a tubular shape by rolling the pattern so as to bring edges 1112 and 1114 together (Figure 12). The edges may then joined as by welding or the like to provide a configuration such as that shown in Figure 13.

The configuration can be seen in these Figures to be made up of a plurality of adjacent segments generally indicated at 1116, each of which is formed in an undulating flexible pattern of substantially parallel struts 1118. Pairs of struts are interconnected at alternating end portions 1119a and 1119b. As is seen in Figure 12, the interconnecting end portions 1119b of one segment are positioned opposite interconnecting end portions 1119a of adjacent segments. The end portions as shown are generally elliptical but may be rounded or square or pointed or the like. Any configuration of end portions is acceptable so long as it provides an undulating pattern, as shown. When the flat form 1110 is formed into an unexpanded tube as

shown in Figure 13, the segments are cylindrical but the end portions 1119 of adjacent segments remain in an opposed position relative to each other.

A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configuration. It may also be chemically etched or EDM'd (electrical discharge machined) to form an appropriate configuration.

Interconnecting elements 1120 extend from one end portion 1119 of one segment 1116 to another end portion 1119 of another adjacent segment 1116 but not to an oppositely positioned end portion 1119 of an adjacent segment 1116. There are at least three struts included between the points on each side of a segment 1116 at which an interconnecting element 1120 contacts an end portion 1119. This results in the interconnecting elements 1120 extending in an angular direction between segments around the periphery of the tubular stent. Interconnecting elements 1120 are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one segment to another extending upwardly in one case and downwardly in another, although all connecting elements between any pair of segments are substantially parallel. Figure 12, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

As a result of this angular extension of the interconnecting elements 1120 between adjacent segments and loops, upon expansion of the stent as seen in Figure 14, the closest adjacent end portions 1119 between segments 1116 are displaced from each other and are no longer opposite each other so as to minimize the possibility of binding or overlapping between segments, i.e., pinching.

The number of interconnecting elements 1120 may vary depending on circumstances in any particular instance. Three per segment are satisfactory for the configuration shown and at least three will be used typically.

The alternate design shown in Figure 15 includes longer struts 1118a in the two end segments 1116a than in the intermediate segments 1116. This allows the end segments (1116a) to have less compression resistance than the intermediate segments (1116), providing a more gradual transition from the native vessel to the

support structure of the stent. Otherwise, the configuration is the same as that shown in Figure 12.

As indicated in the Figures, the invention contemplates a variation of interconnecting element shapes ranging from rectilinear to curvilinear. The invention further contemplates embodiments in which all interconnecting elements are similarly oriented as well as embodiments in which adjacent sets of interconnecting elements extending between adjacent pairs of segments are oppositely oriented (e.g., Figs 7 and 8). The invention also contemplates the use of interconnecting elements which extend from a range of positions along the segments, ranging from various positions in the area in which paired struts are interconnected to other positions along the struts.

The invention also contemplates the possibility of interconnecting elements extending at an oblique angle relative to the longitudinal axis of the stent and connecting adjacent peaks and troughs on adjacent segments as well as peaks and troughs on adjacent segments which are separated by one or more peaks and/or troughs.

The invention also contemplates reversing the orientation of interconnecting elements as shown in Figs. 7 and 8.

Finally, there are preferably at least three interconnecting elements joining adjacent first and second segments although fewer or additional interconnecting elements are also contemplated.

It is understood that the peaks and troughs of the present invention need not be rounded, as shown in the Figures. The peaks and troughs may be bulbous, triangular, square, pointed, or otherwise formed of interconnected straight sections.

As already indicated, this invention is applicable to self-expanding configurations, mechanically expandable configurations and to a wide variety of materials, including both metal and plastic and any other material capable of functioning as an expandable stent. For example, the stent may be of metal wire or ribbon such as tantalum, stainless steel or the like. It may be thin-walled. It may be of shape memory alloy such as Nitinol or the like, etc. The interconnecting elements may be formed integrally with the band-like elements (or segments) or may be bonded thereto via such methods as adhesive bonding, welding or any other known method of bonding.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and this description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are

intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A cylindrical expandable stent comprising:

a plurality of undulating band-like elements, the band-like elements having alternating peaks and troughs, aligned on a common longitudinal axis to define a generally tubular stent body, the peaks and troughs taking a generally longitudinal direction along the cylinder, and

a plurality of interconnecting elements each interconnecting element having a first end and a second end, the first and second ends extending from adjacent band-like elements, the first and second ends displaced circumferentially along the stent.

2. The stent of claim 1, wherein the band-like elements comprise first and second band-like elements, the first band-like elements having a first selected wavelength, the second band-like elements having a second selected wavelength, the second selected wavelength longer than the first wavelength.

3. The stent of claim 2 wherein the first and second band-like elements alternate over the length of the stent and each interconnecting element extends from a first band-like element to a second band-like element.

4. The stent of claim 3 wherein adjacent first and second band-like elements are connected with two or more interconnecting elements.

5. The stent of claim 3 wherein the first band-like elements are characterized by a first amplitude and the second band-like elements are characterized by a second amplitude, the second amplitude greater than the first amplitude.

6. The stent of claim 3 wherein adjacent interconnecting elements extending from peaks on a first band-like element are spaced five peaks apart on the first band-like element.

7. The stent of claim 3 wherein adjacent interconnecting elements extending from a trough on a second band-like element are spaced three troughs apart on the second band-like element.

8. The stent of claim 3 wherein the peaks on the first band-like elements are circumferentially displaced on the periphery of the stent from the troughs on adjacent second band-like elements.

9. The stent of claim 2 wherein interconnecting elements extend from peaks on first band-like elements to troughs on adjacent second band-like elements and from peaks on second band-like elements to troughs on adjacent first band-like elements.

10. The stent of claim 1 wherein each interconnecting element extends from a position intermediate a peak and an adjacent trough on a first band-like element to a position intermediate a trough and an adjacent peak on a second band-like element.

11. The stent of claim 1 wherein adjacent band-like elements are about 180° out of phase with one another.

12. The stent of claim 1 wherein each of the interconnecting elements consists of a first shank, a second shank and a link disposed in-between the first and second shanks, the first shank extending in a longitudinal direction from the peak, the link substantially perpendicular to the first shank, and the second shank extending in a longitudinal direction from the trough and perpendicular to the link.

13. The stent of claim 1 wherein the interconnecting member is substantially perpendicular to the longitudinal axis of the stent.

14. The stent of claim 1 wherein each peak is connected with a second nearest trough on an adjacent band-like element.

15. The stent of claim 1 wherein adjacent band-like elements are about 90° out of phase with one another.

16. The stent of claim 1 wherein the interconnecting elements extend between a peak and a second closest trough on an adjacent band-like element.

17. The stent of claim 1 wherein adjacent band-like elements are connected with five interconnecting elements.

18. The stent of claim 1 wherein adjacent interconnecting elements extending from peaks on a first band-like element are spaced three peaks apart on the band-like elements.

19. The stent of claim 1 wherein the interconnecting elements are rectilinear.

20. The stent of claim 19 wherein the interconnecting elements are straight.

21. The stent of claim 1 wherein the interconnecting elements include a portion which is curvilinear.

22. The stent of claim 1 wherein all of the band-like elements are of the same wavelength.

23. The stent of claim 1 wherein the first and second ends of each interconnecting element are displaced longitudinally along the stent.

24. The stent of claim 1, the band-like elements comprising first and second band-like elements, the first band-like elements having more peaks than the second band-like elements.

25. A tubular, flexible, expandable stent having a longitudinal axis, comprising:

one or more cylindrical shaped first segments, each first segment having first struts having first and second ends, the first segment being defined by a member formed in an undulating pattern of interconnected paired first struts and in which adjacent pairs of first struts in a given first segment are interconnected at opposite ends,

one or more cylindrical shaped second segments, each second segment being defined by a member formed in an undulating pattern of interconnected paired second struts and in which adjacent pairs of second struts in a given second segment are interconnected at opposite ends,

the first struts being shorter than the second struts,

the first segments formed of a number of first struts and the second segments formed of a number of second struts, the number of first struts in a first segment exceeding the number of second struts in a second segment.

the first and second segments aligned on a common longitudinal axis to define a generally tubular stent body, the first and second segments present along the stent body, and

adjacent first and second segments connected by a plurality of interconnecting elements, each interconnecting element having a first end and a second end, each interconnecting element extending from an end of paired first struts on a first segment to an end of paired second struts on an adjacent second segment, each first end of an interconnecting element displaced circumferentially along the stent from each second end of an interconnecting element.

26. The stent of claim 25 where each first end of an interconnecting element is longitudinally displaced from each second end of an interconnecting element.

27. The stent of claim 25 where there are at least three interconnecting elements joining adjacent first and second segments.

28. The stent of claim 25 where adjacent interconnecting elements are separated by five pairs of first struts on the first segments and three pairs of second struts on the second segments.

29. The stent of claim 1 formed of a metal.

30. The stent of claim 29 wherein the metal is a shape memory alloy.

31. The stent of claim 1 wherein the stent is a thin-walled tubular member.

32. The stent of claim 1 in a self-expanding configuration.

33. The stent of claim 1 in a mechanically expandable configuration.

34. The stent of claim 1 comprising interconnecting elements of a plurality of different lengths.

35. The stent of claim 34 wherein adjacent band-like elements are interconnected by interconnecting elements of more than one length.

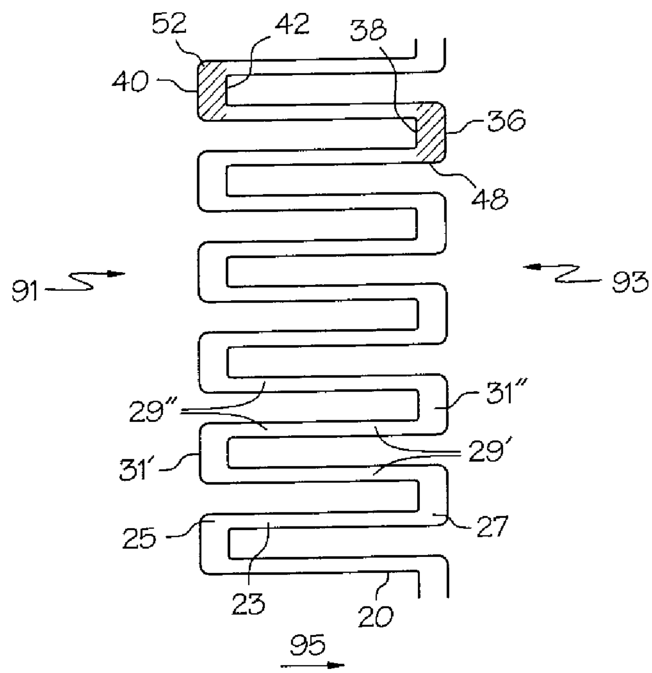
36. The stent of claim 1 comprising band-like elements whose wavelength varies along the band-like element.

37. The stent of claim 1 comprising band-like elements whose amplitude varies along the band-like element.

Abstract of the Disclosure

IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

Segmented articulatable stent of open structure comprised of end-connected struts of first and second lengths making up first and second segments with angular interconnects between adjacent first and second segments.


52
42
38
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36
48
91
93
31"
29"
29'
31'
27
25
23
20
95

FIG. 1a

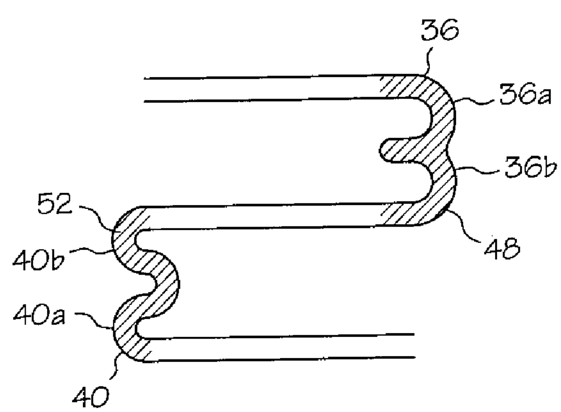
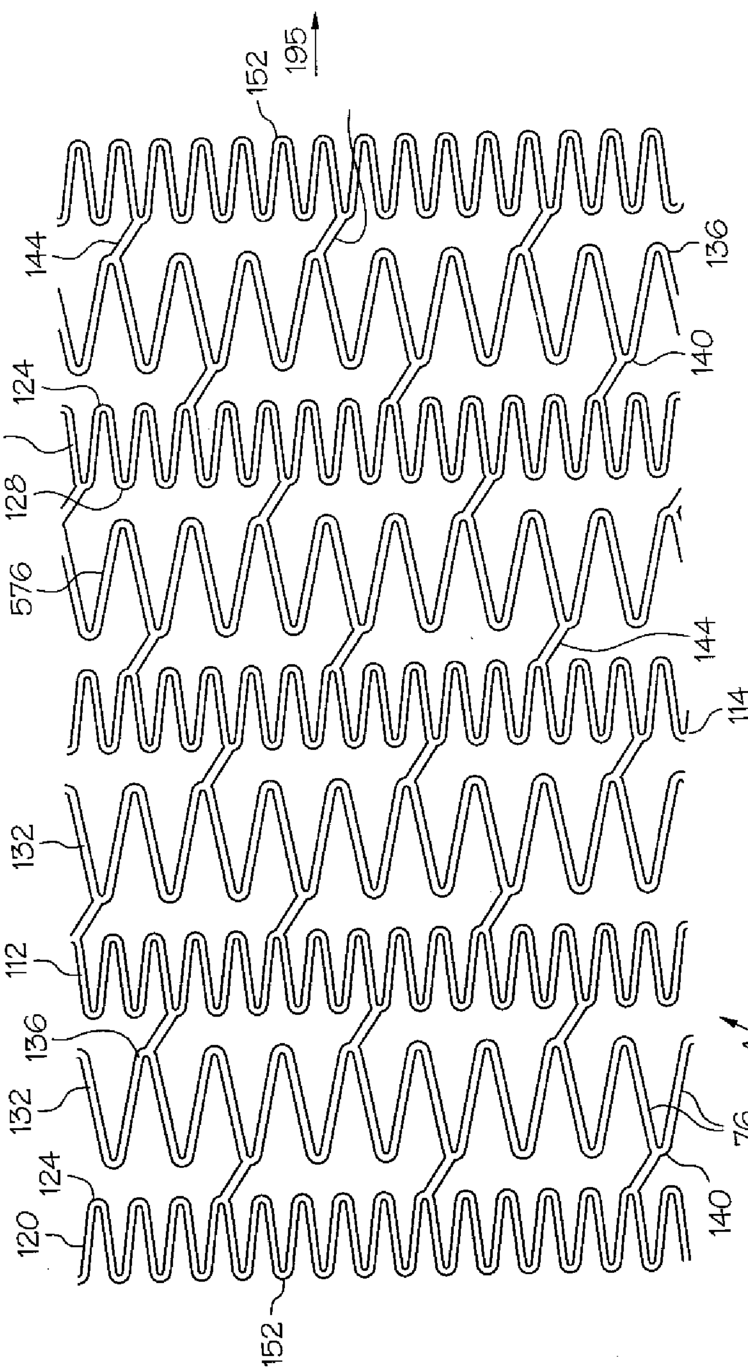

36
36a
36b
52
48
40b
40a
40

FIG. 1b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195
144
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576
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114
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152

FIG. 2

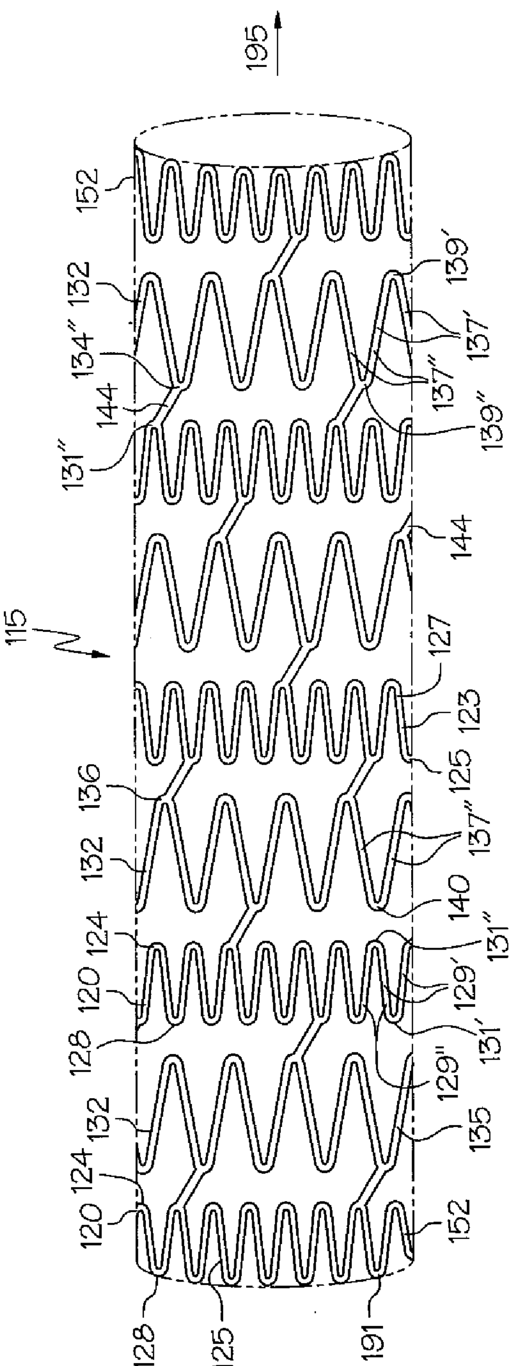

195
152
132
134"
144
131"
139'
137'
137"
139"
144
115
127
123
125
136
132
137"
140
131"
124
120
128
129'
131'
129"
132
135
124
120
152
128
125
191

FIG. 3

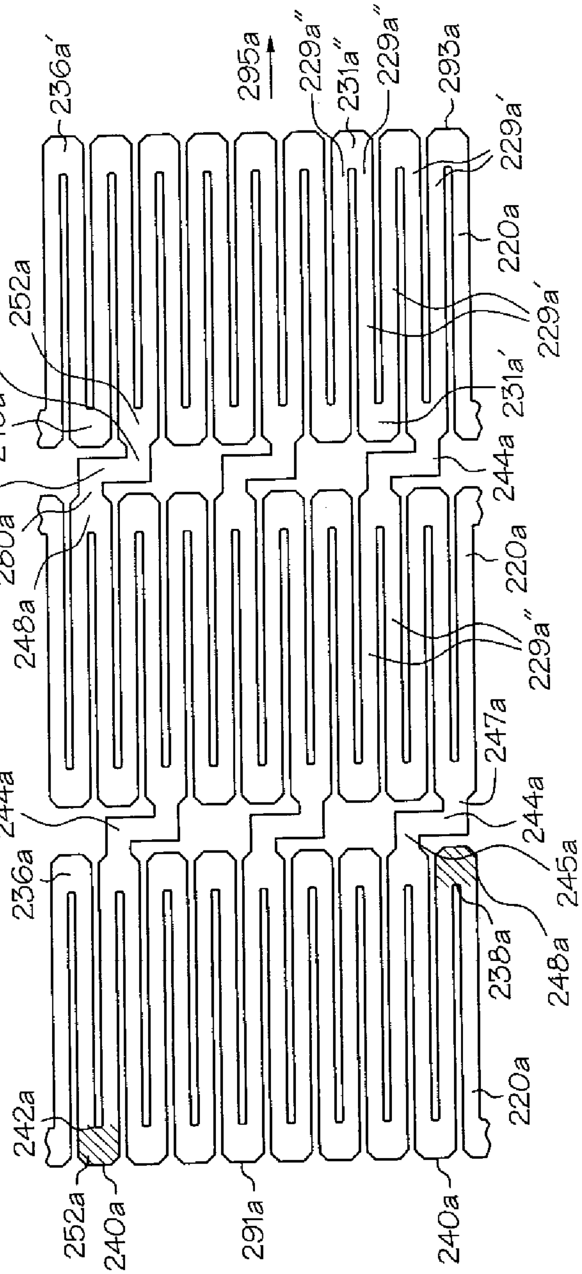
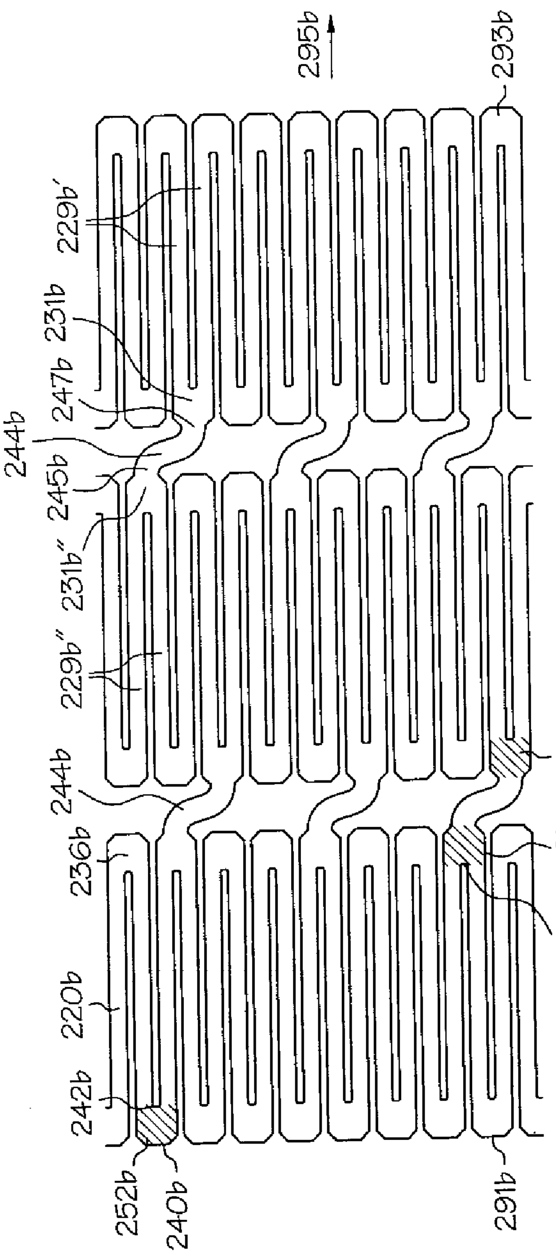

236a'
295a
229a"
231a"
229a"
293a
229a'
284a
252a
220a
229a'
240a
231a'
288a
244a
280a
220a
248a
229a"
244a
247a
236a
244a
245a
238a
248a
242a
220a
252a
240a
291a
240a

FIG. 4a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293b
229b'
231b
247b
244b
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244b
236b
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242b
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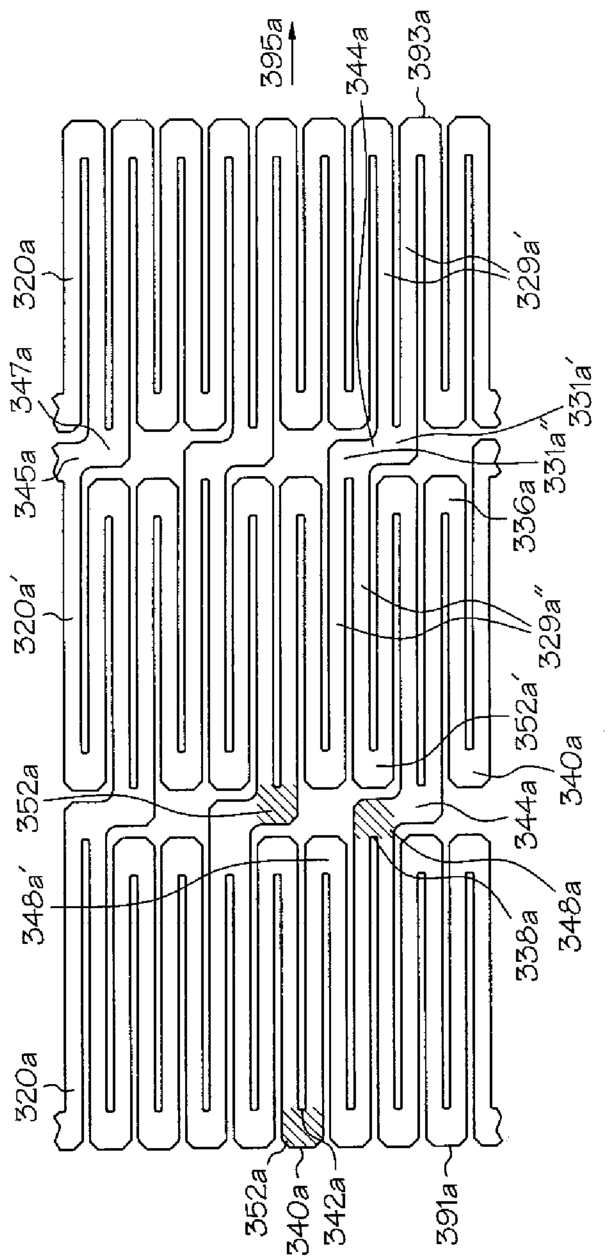
248b
242b

FIG. 4b


395a
344a
393a
320a
329a'
347a
331a'
331a''
345a
336a
320a'
329a''
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344a
348a'
338a
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320a
352a
340a
342a
391a

FIG. 5a

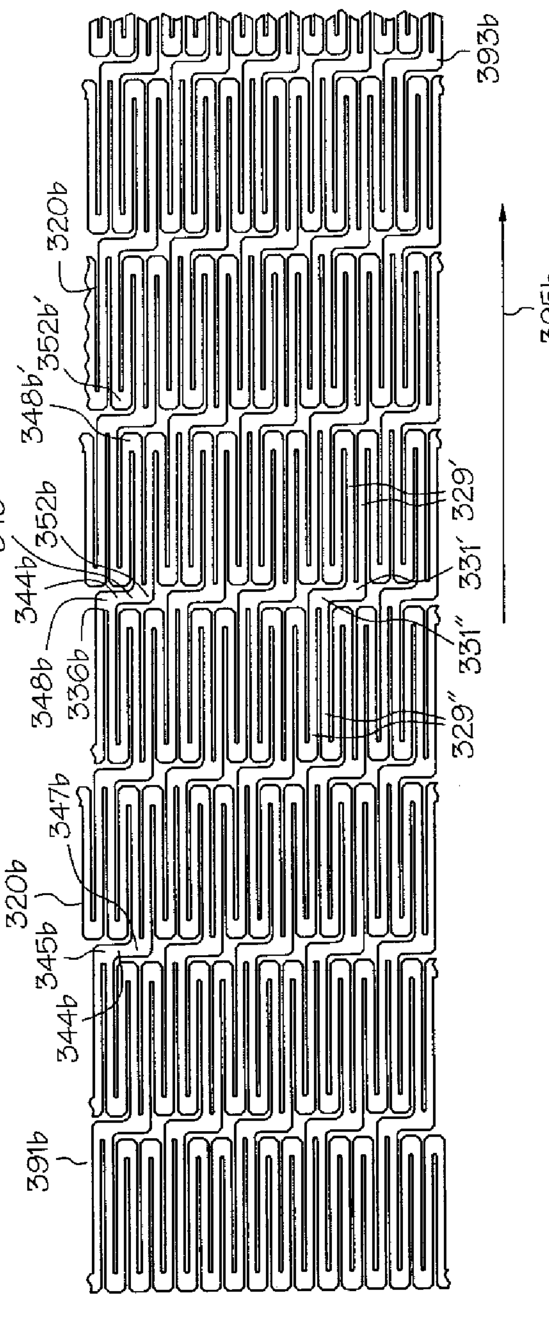

393b
320b
352b'
348b'
340
352b
344b
348b
336b
329'
331'
331"
329"
347b
320b
345b
344b
391b
395b

FIG. 5b

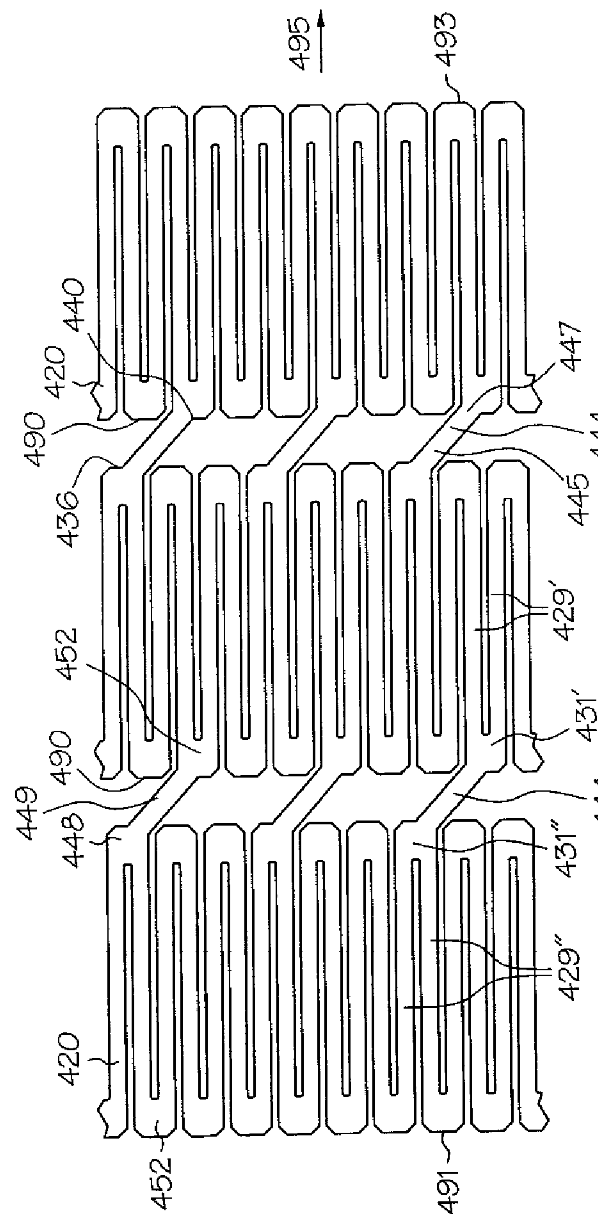

495
493
440
420
490
436
447
444
445
452
429'
431'
449
448
490
444
431"
429"
420
452
491

FIG. 6

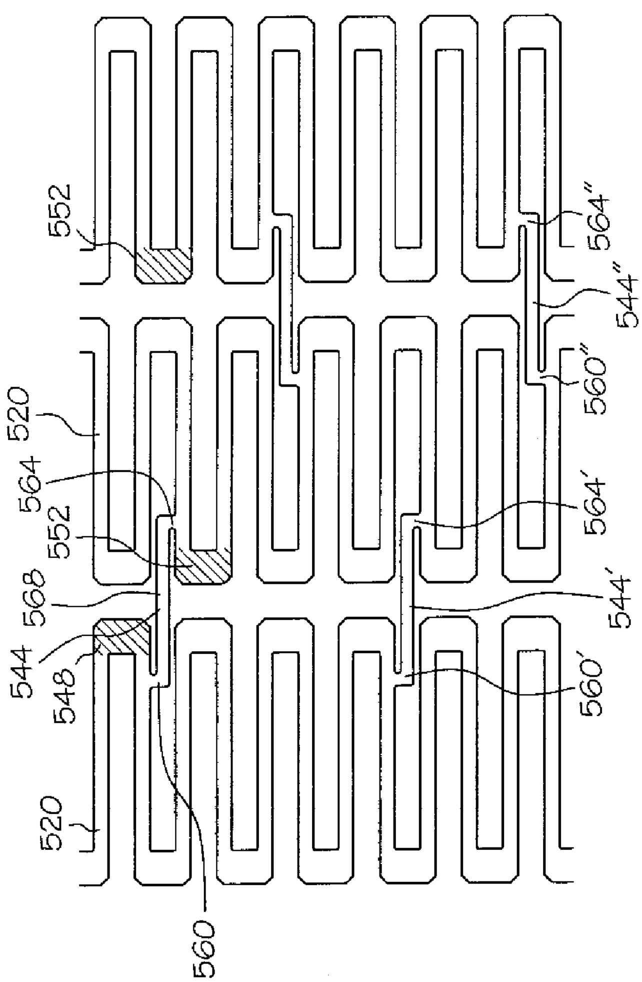
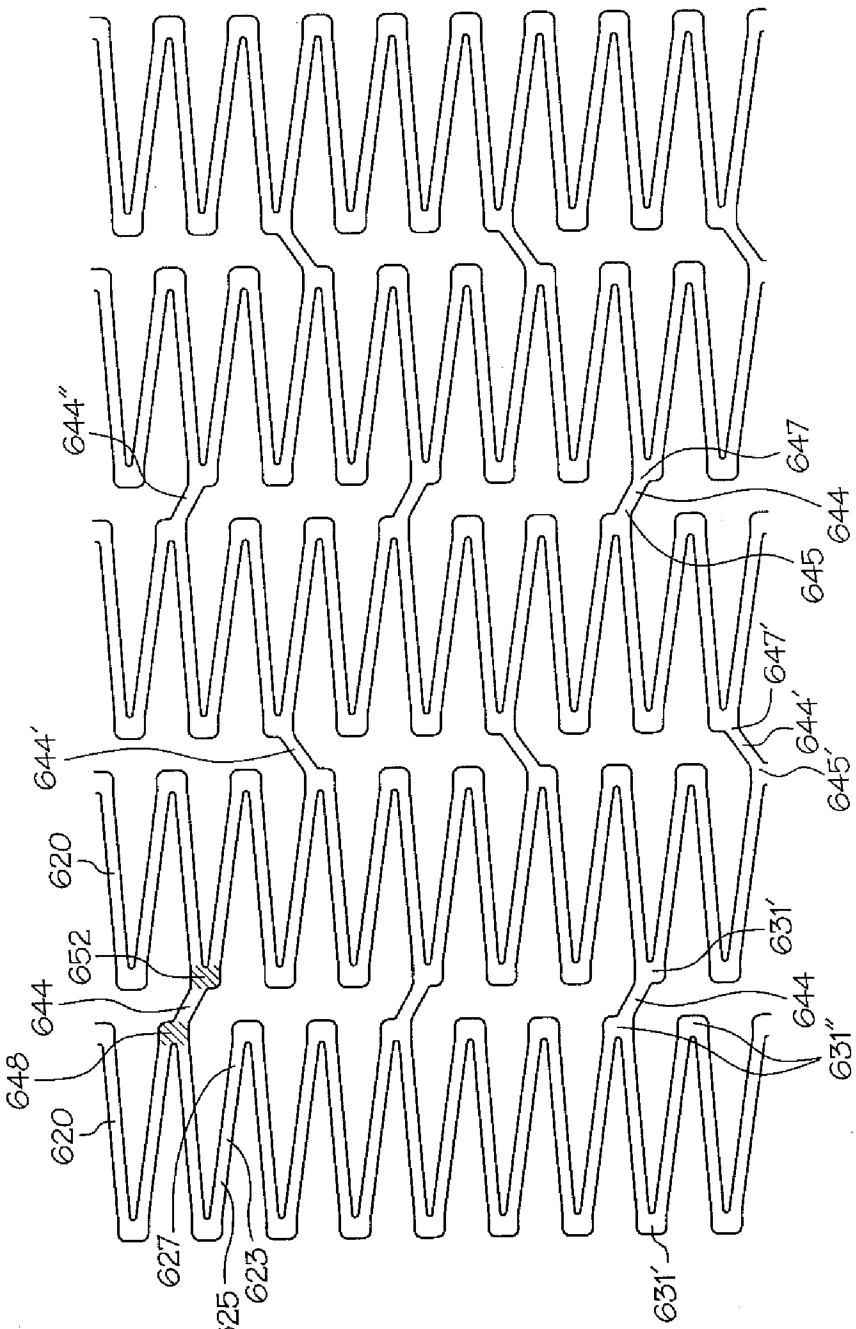


FIG. 7



644"
647
644
645
644'
647'
644'
645'
620
652
644
648
620
631'
644
631"
627
625
623
631'

FIG. 8

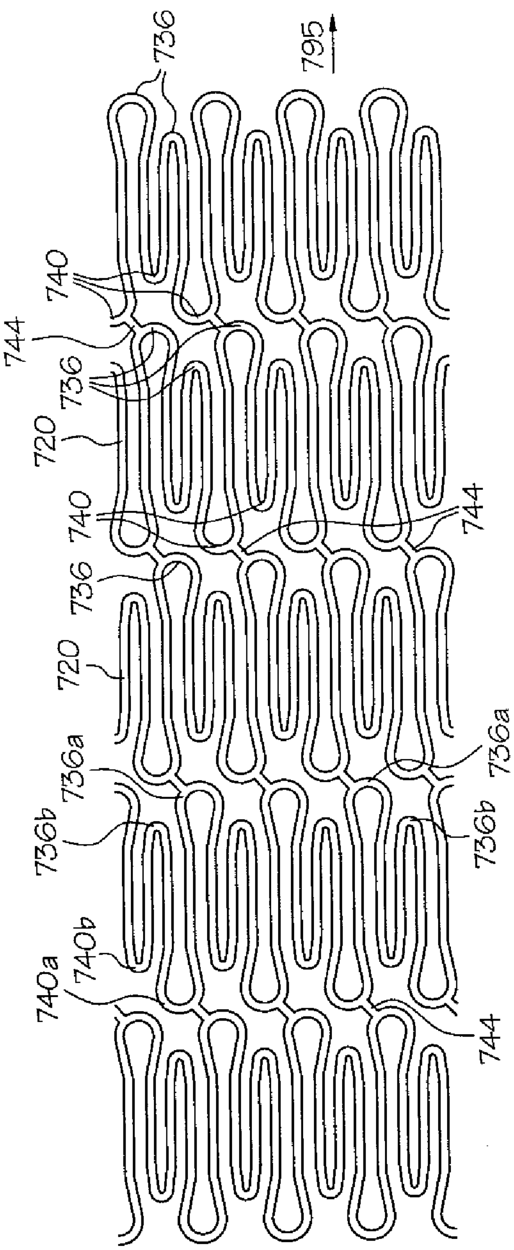

736
795
740
744
736
720
740
744
736
720
736a
736a
736b
736b
740a
740b
744

FIG. 9

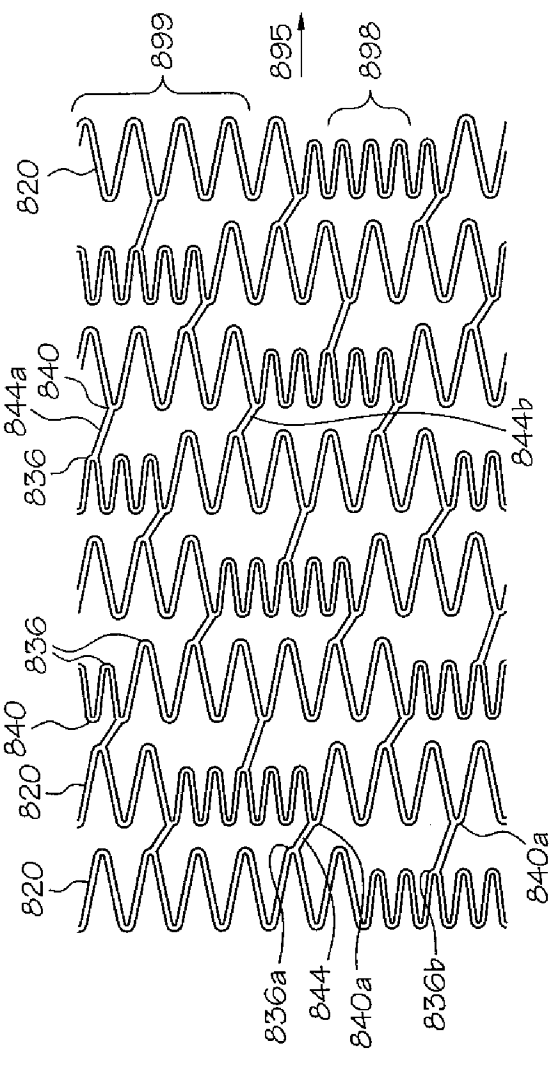

899
895
898
820
836
844a
840
844b
836
840
820
820
836a
844
840a
836b
840a

FIG. 10

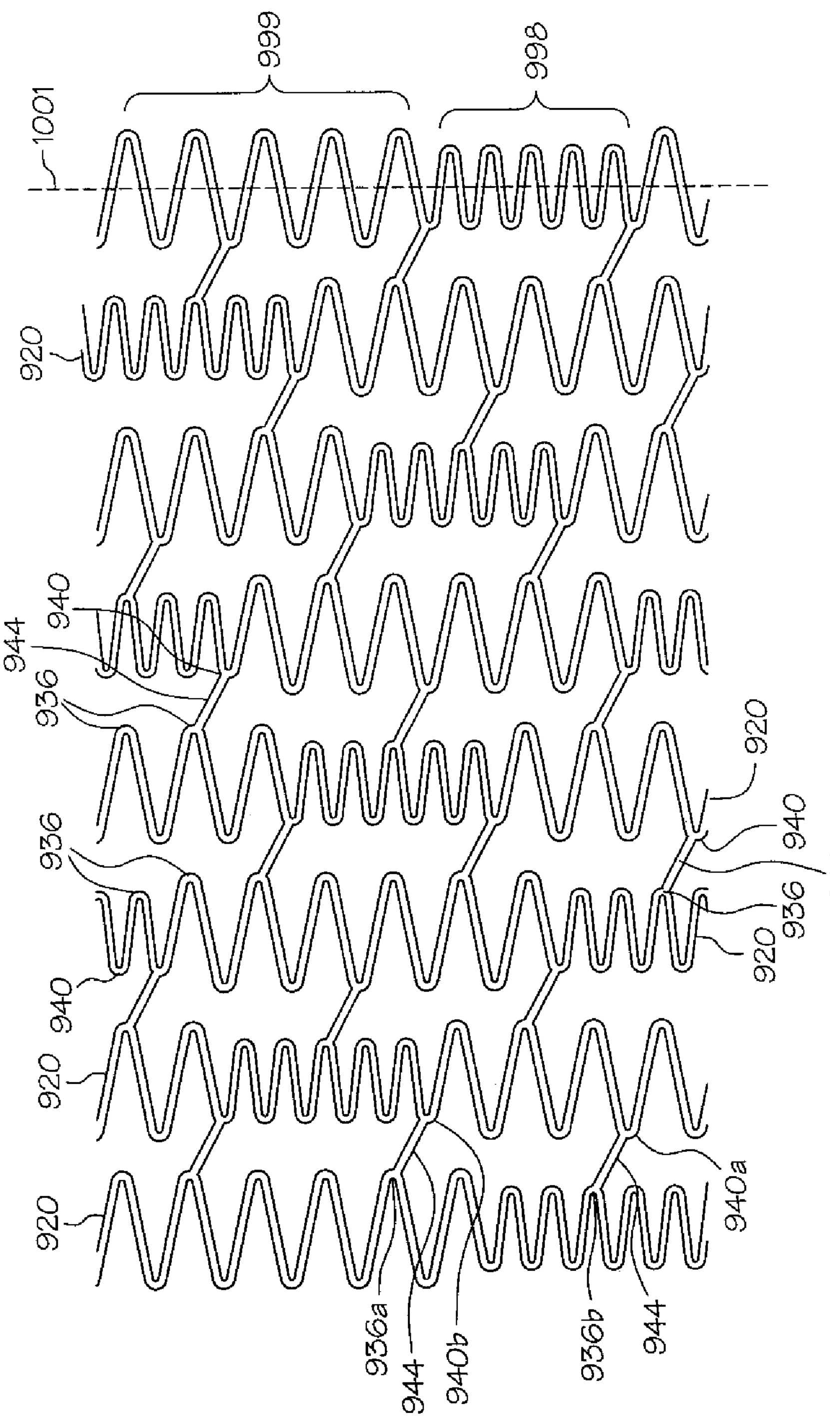

999
998
1001
920
944
940
936
936
940
940
920
920
920
940
944
936
920
936a
944
940b
936b
944
940a

FIG. 11

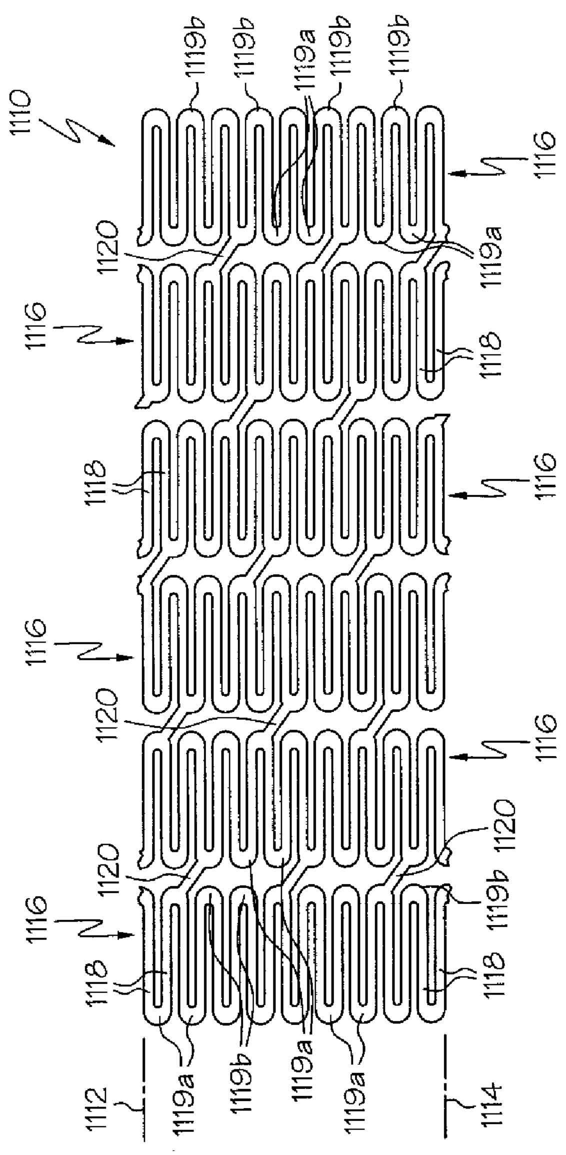


FIG. 12

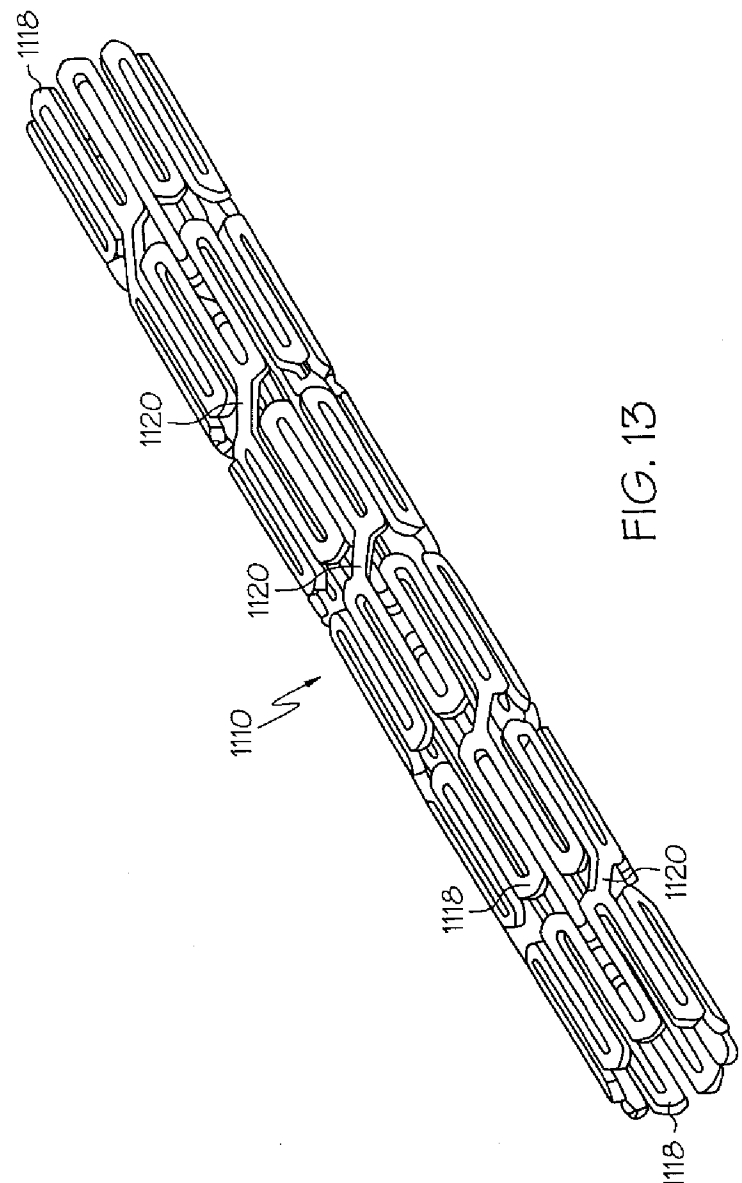


FIG. 13

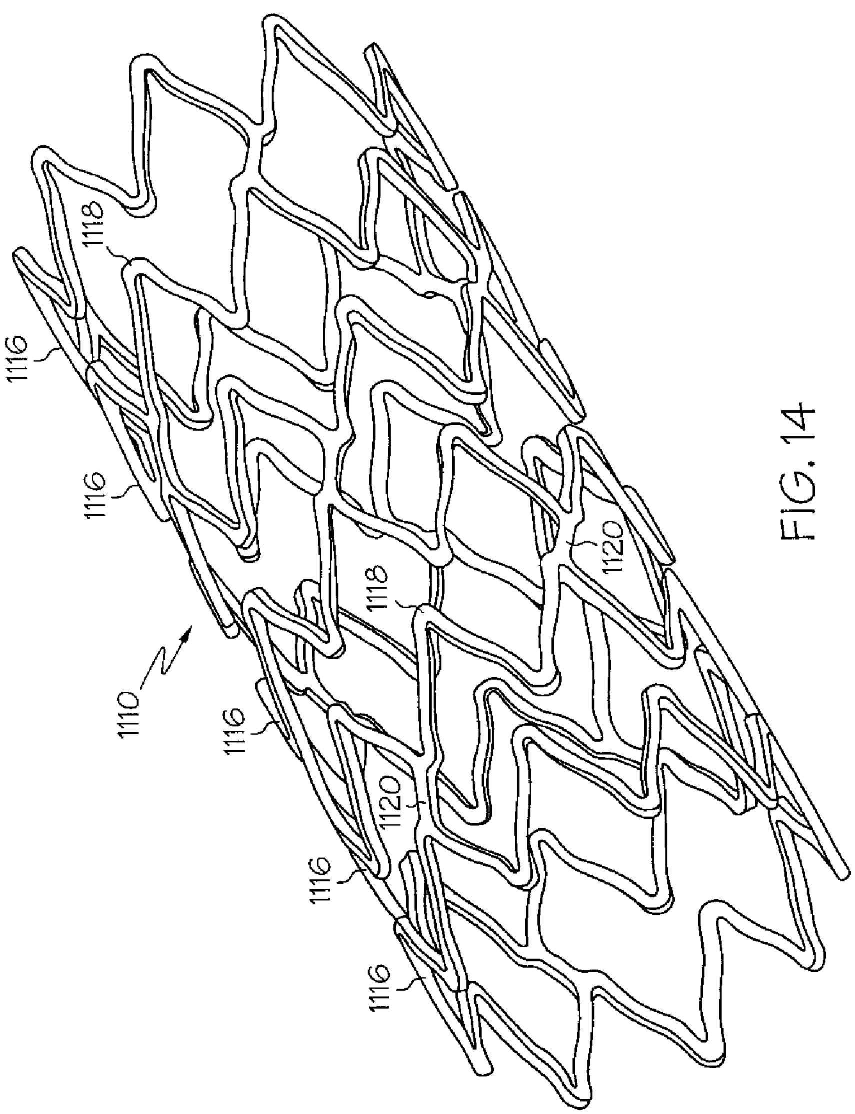


FIG. 14

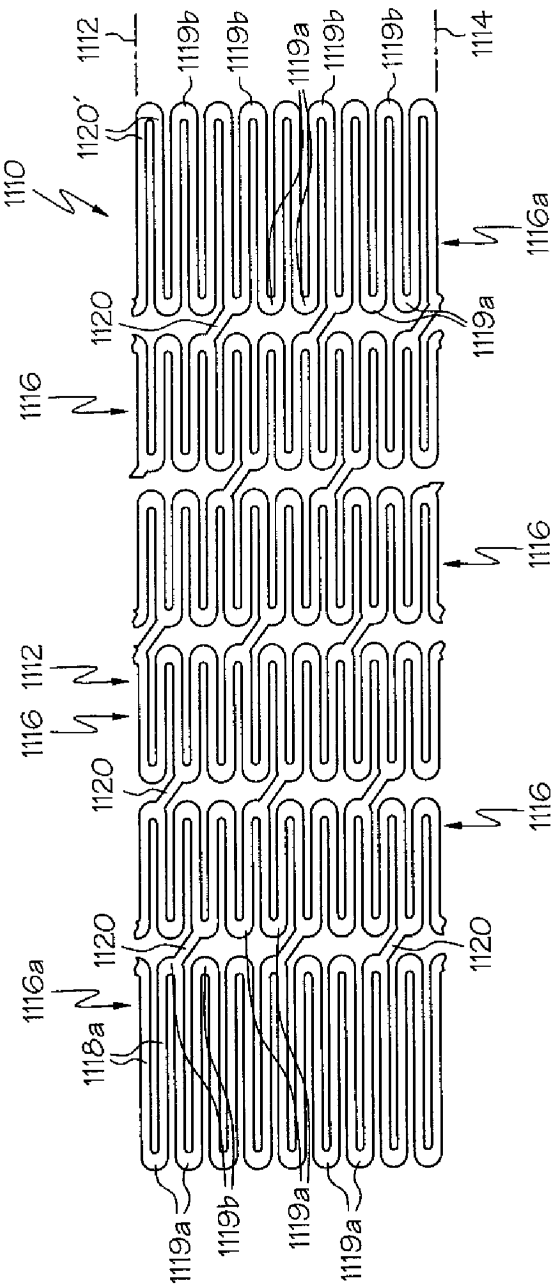


FIG. 15

Appendix B – Preliminary Amendment Filed on November 10, 2003

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Brown et al.**
Application No.:	**Not yet assigned**
Filed:	**Concurrently Herewith**
For:	**Improved Longitudinally Flexible Expandable Stent**
Examiner:	**Not yet assigned**
Group Art Unit:	**Not yet assigned**

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2N-6769-US03

PRELIMINARY AMENDMENT

This Amendment is part of a Continuation Application filed concurrently herewith. Before beginning examination and calculating the fees in this application, please amend the above-identified application as indicated below:

Amendments to the Specification

On page 1 of the application please replace the paragraph starting on line 3 with the following amended paragraph and section heading:

Cross-Reference to Related Applications

This application is a Continuation Application of U.S. Application No. 09/197,278, filed November 20, 1998, which is a Continuation-in-Part of application Serial No. 08/511,076, filed August 3, 1995, which is a Continuation-in-Part Application of U.S. Application No. 08/396,569, filed March 1, 1995 and now abandoned, the disclosure of all ~~which is~~ hereby incorporated by reference.

Amendments to the Claims

1-37. (Cancelled)

38. (New) A stent in the form of a thin-walled, cylindrical tube with a longitudinal axis, the stent comprising:

a multiplicity of interior circumferential sets of strut members and one end circumferential set of strut members at each of the two longitudinal ends of the stent;

each interior circumferential set of strut members including at least one connected strut member consisting of a long diagonal section having a longitudinal length fixedly attached to a connected curved section, each connected curved section being joined by means of a longitudinal connecting link to one connected curved section of an adjacent circumferential set of strut members and all connecting links that connect adjacent circumferential sets of strut members are connected at a connected curved section, each interior set of strut members also including at least one unconnected strut member consisting of a short diagonal section having a longitudinal length fixedly joined to an unconnected curved section.

39. (New) The stent of claim 38 wherein the longitudinal connecting link is straight.

40. (New) The stent of claim 38 wherein the longitudinal connecting link is an undulating, flexible, longitudinal connecting link.

41. (New) The stent of claim 40 wherein the place where each flexible longitudinal connecting link is joined to the interior set of strut members is near the connecting line where a connected curved section is joined to a diagonal section.

42. (New) The stent of claim 38 wherein there are three longitudinal connecting links that join each adjacent pair of circumferential sets of strut members.

43. (New) The stent of claim 38 wherein there are five longitudinal connecting links that join each adjacent pair of circumferential sets of strut members.

44. (New) The stent of claim 38 wherein the total longitudinal length in the longitudinal direction of each end circumferential set of strut members is shorter than the longitudinal length in the longitudinal direction of each interior circumferential set of strut members.

45. (New) The stent of claim 38 wherein the metal from which the stent is formed in

stainless steel.

46. (New) The stent of claim 38 wherein the metal from which the stent is formed is tantalum.

47. (New) A stent in the form of a thin-walled, cylindrical tube with a longitudinal axis, the stent comprising:

a multiplicity of interior circumferential sets of strut members and one end circumferential set of strut members at each of the two longitudinal ends of the stent;

each interior circumferential set of strut members including at least one connected strut member consisting of a long diagonal section having a longitudinal length fixedly attached to a connected curved section, each connected curved section of an adjacent means of a longitudinal connecting link to one connected curved section of an adjacent circumferential set of strut members; each interior set of strut members also including at least one unconnected strut member consisting of a short diagonal section having a longitudinal length fixedly joined to an unconnected curved section; and

the stent being further characterized by having the length of each diagonal section being longer than the length of each short diagonal section and for each interior circumferential set of strut members, the number of connected curved sections being equal to the number of unconnected curved sections.

48. (New) A stent in the form of a thin-walled, cylindrical tube with a longitudinal axis, the stent comprising:

a multiplicity of interior circumferential sets of strut members and one end circumferential set of strut members at each of the two longitudinal ends of the stent;

each interior circumferential set of strut members including at least one connected strut member consisting of a long diagonal section having a longitudinal length fixedly attached to a connected curved section, each connected curved section being joined by means of a longitudinal connecting link to one connected curved section of an adjacent circumferential set of strut members and all connecting links that connect adjacent circumferential sets of strut members are connected at a connected curved section; each interior set of strut members also including at least one unconnected strut member consisting of a short diagonal section having a longitudinal length fixedly joined to an unconnected curved section; and

the stent being further characterized by having the length of each long diagonal section being longer than the length of each short diagonal section, so that the unconnected strut members have a decreased tendency for flaring outward as the stent is advanced though a curved vessel.

49. (New) The stent of claim 48 wherein the longitudinal connecting link is straight.

50. (New) The stent of claim 48 wherein the longitudinal connecting link is an undulating, flexible, longitudinal connecting link.

51. (New) The stent of claim 50 wherein the place where each flexible longitudinal connecting link is joined to the interior set of strut members is near the connecting line where a connected curved section is joined to a diagonal section.

52. (New) The stent of claim 48 wherein there are three longitudinal connecting links that join each adjacent pair of circumferential sets of strut members.

53. (New) The stent of claim 48 wherein there are five longitudinal connecting links that join each adjacent pair of circumferential sets of strut members.

54. (New) The stent of claim 48 wherein the total longitudinal length in the longitudinal direction of each end circumferential set of strut members is shorter than the longitudinal length in the longitudinal direction of each interior circumferential set of strut members.

55. (New) The stent of claim 48 wherein the metal from which the stent is formed in stainless steel.

56. (New) The stent of claim 48 wherein the metal from which the stent is formed is tantalum.

REMARKS

As indicated above claims 1-37 are cancelled. Claims 1-37 are hereby cancelled without prejudice or disclaimer. New claims 38-56 are presented above. Support for the claims may be found in the Application as originally filed, and more specifically, at least in: FIGs. 2, 4a-4b, 7 and 5b. No new matter has been added by the above amendments.

In accordance with 37 CFR 1.607 claims 38-48 correspond substantially to claims presented in U.S. 6,540,775 to Fischell et al., issued April 1, 2003 and are presented herein in order to provoke an interference with the U.S. 6,540,775 patent.

Though not copied, instant claims 38-41 correspond substantially to claims 1-4 of the 6,540,775 reference, instant claims 42-43 correspond substantially to claims 7-8 of the 6,540,775 reference, and instant claims 44-46 correspond substantially to claims 10-12 of the 6,540,775 reference.

Instant claim 47 is copied from claim 14 of the 6,540,775 patent.

Instant claim 48 is an alternative to instant claim 38 and likewise corresponds substantially to claim 1 of the 6,540,775 reference. Instant claims 49-52 are dependent from instant claims 48 and correspond substantially to claims 1-4 of the 6,540,775 reference. Instant claims 52-53 are also dependent from instant claim 48 and correspond substantially to claims 7-8 of the 6,540,775 reference. Instant claims 54-56 are dependent from instant claim 48 and correspond substantially to claims 10-12 of the 6,540,775 reference.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

Date: November 10, 2003

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Related Proceedings Appendix - Decision from BPAI for Application No. 08/511,076 mailed on September 25, 2001

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BRIAN J. BROWN and MICHAEL L. DAVIS

Appeal No. 1998-0022
Application No. 08/511,076

ON BRIEF

Before CALVERT, ABRAMS, and BAHR, Administrative Patent Judges.

ABRAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-10, which are all of the claims pending in this application.

We AFFIRM.

BACKGROUND

The appellants' invention relates to a stent for implantation within a body vessel. An understanding of the invention can be derived from a reading of exemplary claim 10, which appears in the appendix to the Brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Palmaz	5,102,417	Apr. 7, 1992
Lau et al. (Lau) (European Patent Application)	540,290	May 5, 1993

Claims 1-7, 9 and 10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lau.

Claims 1-7, 8, 9 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Lau in view of Palmaz.[1]

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the Answer (Paper No. 11) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 10) for the appellants' arguments thereagainst.

---

[1] In both the final rejection and the Answer, the rejection of claim 8 was separately recited as "Lau et al and Palmaz as applied to claims 1-7 and 9-10 above, and further in view of Lau et al (EP 0540290)." However, only one Lau reference has been listed by the examiner, and it is EP 0540290.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The Rejection Under Section 102

At the outset, we note with regard to the anticipation rejection that the appellants have chosen to group together claims 1-7, 9 and 10 (Brief, page 7). Therefore, these claims will stand or fall with representative claim 10. See 37 CFR 1.192(c)(7) and Section 1206 of the Manual of Patent Examining Procedure.

Anticipation under Section 102 is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of the claimed invention. See In re Paulsen, 30 F.3d 1475, 1480-1481, 31 USPQ2d 1671, 1675 (Fed. Cir. 1994) and In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). Anticipation by a prior art reference does not require either the inventive concept of the claimed subject matter or recognition of inherent properties that may be possessed by the reference. See Verdegaal Brothers Inc. v. Union Oil Co. of California, 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987). It does not require that the reference teach what the applicant is claiming, but only that the claim on appeal "read on" something disclosed in the reference, that is, all

limitations of the claim are found in the reference. See Kalman v. Kimberly-Clark Corp, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert denied, 465 U.S. 1026 (1984).

It is the examiner's position that all of the subject matter recited in claim 10 is disclosed or taught by Lau. The only argument offered by the appellants in rebuttal to this conclusion is that their claims require that the angular interconnecting elements which connect together adjacent segments of the stent "are not parallel to the longitudinal axis of the stent," a condition which they urge is not met by the embodiment shown in Figure 11 of Lau, in which the interconnecting elements are parallel to the longitudinal axis of the stent (Brief, pages 7 and 8).

Claim 10 recites a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body with

> each segment being defined by a member formed in an undulating pattern of interconnected paired struts . . . in which adjacent pairs of struts in a given segment are interconnected at only one end in an alternating arrangement, the interconnected ends of each pair in each segment alternating between ends of pairs and the interconnected ends of the strut pairs of one segment being positioned substantially opposite to the interconnected ends of an adjacent segment (emphasis added).

The claim goes on to recite "a plurality of interconnecting elements each extending angularly from one segment to an adjacent segment" (emphasis added). From our perspective, since each segment is defined in claim 10 as a member including a portion which interconnects the ends of adjacent struts, an interconnecting element that

angularly extends from "a segment" to "an adjacent segment" meets the literal language of the claim if it extends at an angle from any portion of the first segment. Our position is best explained by relating this to the embodiment shown in Figure 11 of Lau. It is our view that Lau's elements 13, which interconnect adjacent segments of the stent, are "extending angularly from one segment to an adjacent segment" (emphasis added), as recited in the claim, in that they are at an angle (90 degrees) to the U-shaped portions of each segment that connects the ends of adjacent struts. It is true that elements 13 are oriented parallel to the longitudinal axis of the Lau stent, however, the fact is that claim 10 is devoid of language which would limit "angularly" to mean that the angle is measured with respect to the longitudinal axis of the stent, or would require it to be so interpreted.

It therefore is our conclusion that all of the language in representative claim 10 reads on the stent disclosed in Lau's Figure 11, and thus the reference anticipates the claim. We are not persuaded otherwise by the appellants' argument, which simply is not commensurate with the scope of the language in the representative claim.

The rejection of representative claim 10 and claims 1-7 and 9, which have been grouped therewith, as being anticipated by Lau is sustained.

The Rejections Under Section 103

Claims 1-7, 9 and 10 also stand rejected as being unpatentable over Lau in view of Palmaz. Again, the appellants have chosen to group these claims together and, as

before, we have selected claim 10 to be the representative claim. As far as this rejection is concerned, we determined above that claim 10 is anticipated by Lau and, since anticipation is the epitome of obviousness,[2] we also will sustain the Section 103 rejection of claims 1-7, 9 and 10.

The same reasoning applies to claim 8, the separate patentability of which was not argued in the Brief (page 11), and we also will sustain the Section 103 rejection of this claim.

CONCLUSION

All of the rejections are sustained.

The decision of the examiner is affirmed.

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[2] In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

IAN A. CALVERT
Administrative Patent Judge

NEAL E. ABRAMS
Administrative Patent Judge

JENNIFER D. BAHR
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

NEA:pgg

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